Cost consequence analysis of facility-based lay health worker intervention to improve hypertension management in rural South Africa

A Research Report submitted to the School of Public Health, Faculty of Health Sciences, University of the Witwatersrand, in partial fulfilment of the requirements for the degree of

Master of Public Health in the field of Health Economics

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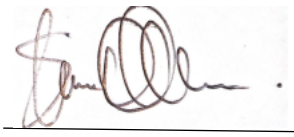
Declaration

I, Dineo Mothlele, declare that this Research Report is my own, personal work. It is being submitted for the Degree of Master of Public Health in Health Economics at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

Signed,



_____Mrs D, Mothlele

On the 23rd of November 2021, in Johannesburg.

Dedication

I dedicate this research to my husband, Tshepiso Mothlele and to my children, Onalerona (2years old) and Arenea-Nala (8 months old). I dedicate this to my mother - Agrinette Khakhane, father - Sello Khakhane and siblings - Thope, Lebogang and Keketso Khakhane. And finally, this research is also dedicated to all the mothers out there – this is to show that you should not give up on your dreams!

Abstract

Introduction

In the year 2011, the South African government introduced the Integrated Chronic Disease model (ICDM) as one of the primary healthcare reforms. The model aimed to improve operational efficiency in primary healthcare facilities and to improve health outcomes for patients living with chronic communicable and non-communicable diseases (NCDs), achieved through reduction of patient waiting times and patient load. However, as this was a nurse-led initiative, this meant that nurses had to take on additional tasks like scheduling appointments, defaulter tracing and prepacking medications for patients. Resultantly, due to the shortage of health care personnel in facilities, nurses struggled to handle the additional workload which then affected quality of health care.

Healthcare personnel shortages continue to be a global health systems problem. In South Africa alone, the physician density ratio in 2017 was estimated at 0.91 per 1000 population while nursing and midwifery personnel ratio were 3.51 per 1000 population. This in turn affected public health care facilities especially rural primary health facilities causing increased waiting times, poor chronic disease management and decreased clinic attendance.

As part of reorientation of services to support the Integrated Chronic Disease Model (ICDM), the Nkateko trial implemented a lay health worker intervention, in rural Mpumalanga. The trial was a task shifting intervention which aimed to improve hypertension health outcomes, in rural Mpumalanga. Tasks were shifted from nurses to lay health workers (re-organisation of health services). The trial had a process evaluation which sought to understand the impact of the use of lay health workers on integrated chronic care for patients with hypertension and how the use of such a cadre of workers would modify patient outcomes. This paper reports on the study that assessed the cost and consequences associated with using lay health workers to improve management of hypertension in rural South Africa within the Nkateko Randomized Controlled Trial (RCT).

Methods

Costs associated with deploying lay health care workers in the Nkateko trial were prospectively recorded, including costs of training. An activity-based approach also called the ingredients-based approach was used to select cost data to include in the analysis. Costs were categorised into capital and recurrent costs. Expenditure data, collected between the years 2014 to 2015 during the RCT, was used as the primary source of cost data. The cost analysis was performed from a health provider perspective using South African Rands (R). Final costs were presented in 2015 prices.

Due to the different outcomes assessed in the primary study, a cost consequence analysis was chosen as the method of economic evaluation. Typically, a cost-consequence analysis (CCA) calculates and presents estimates of resource use alongside the benefits (clinical or financial) as separate domains. The benefits (intermediate health outcomes) presented in this CCA were derived from the primary study and include clinic attendance and waiting times. A traditional literature search (not a systematic review) was conducted to understand the potential financial and health consequences of improving hypertension outcomes, using recent research papers and publications from the period 2013 to 2020. These were presented on a cost-consequence table.

Results

The study showed that to roll-out the intervention it cost R1 308 605 ($102 459) (in two years) across four clinics. There were no significant differences in the total cost of intervention across all four intervention clinics. However, the cost per person per health facility ranged from R3.59 to R12,66 (which was almost triple the cost where patients who attended clinics were fewer). Timber clinic had the highest cost whilst the other three clinics were almost the same. This was due to the reduction in patient numbers in Timber. Total capital costs for the period of 2 years in the intervention amounted to R17 770($1 391). This makes up about 1.4% of the total intervention costs. Recurrent costs made up 87.9% (R1 148 555) of the total intervention costs. The lay heath worker intervention showed an improvement in clinic attendance and improvement attendance on scheduled dates. Part of the descriptive and financial consequences includes

increased hypertension awareness, and potential costs (R2.5 – R4.2million) saved on stroke treatment in the Mpumalanga region, respectively.

Conclusion

This study estimated the costs associated with the use of lay health workers in the context of the Nkateko trial. The study showed that using lay health workers offers a potentially promising low-cost means to intervene to significantly reduce waiting times at health facilities and to improve intermediate health outcomes in patients with hypertension. Future research should explore the relationship between intermediate health outcomes reported in this study and final health outcomes (e.g. stroke prevention) through, potentially, modelling techniques.

Acknowledgements

Firstly, I would like to thank God for blessing me with the opportunity to enrol at the Wits School of Public Health to study for this Master of Public Health in Health Economics. It has always been my dream to find myself in such a space, it's true that He knows the desires of our hearts. He kept me going through the challenging times and in moments when I felt like giving-up He was my strength.

Psalms 137:4 (NIV)

"*Take delight in the LORD, and he will give you the desires of your heart*."

To my husband, Mr Tshepiso Mothlele, thank you for always showing me support and for always believing in me. Thank you for being there to take care of our children whenever I was not able to do that and for always lifting me up whenever I felt down or demotivated. Thank you for investing in my dream. I am forever thankful for you and your amazing support. I love you. To my children, Onalerona and Arenea-Nala Mothlele, thank you for inspiring me to work hard, for the love and support. I love you.

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To my sponsor, Services-SETA, thank you for the financial assistance you have provided in the first 2 years of my studies. Thank you for making sure I fulfil my dreams. I pray that one day I will be able to pay it forward for others to fulfil their dreams.

Table of Contents

List of Figures

List of Tables

List of Abbreviations

BP	Blood Pressure
DALYs	Disability-Adjusted Life Years
CBA	Cost Benefit Analysis
CUA	Cost Utility Analysis
CHW	Community Health Worker
CVD	Cardiovascular Disease
GDP	Gross Domestic Product
HDSS	Health Demographic and Surveillance System
HIV	Human Immuno-deficiency Virus
HREC	Human Research Ethics Committee
ICCC	Innovative Care for Chronic Conditions
ICDM	Integrated Chronic Disease Management
LMICs	Low-Middle Income Countries
NCDs	Non-Communicable Diseases
NDoH	National Department of Health
NHI	National Health Insurance
PHC	Primary Heath Care
PMTC	Prevention of Mother to Child Transmission Services
RCT	Randomized Controlled Trial
SCIP	Specialized Community health workers Package
SMS	Short Message Service
WBOTs	Ward-Based Outreach Teams
WEF	World Economic Forum
WHO	World Health Organization

Nomenclature

Lay Health Worker/Community Health Worker:	Refer to men or women who work as health workers but who have no formal professional tertiary education therefore not regarded as professional health workers. However, they are informally trained based on the needs of the intervention (Lewin et al., 2006). They are usually members of the community they work in (Rifkin, 2016). Although they are not seen as health care professionals, they receive some form of basic training to help in the provision of selected healthcare services and promotion (Nkonki et al., 2011). For the purposes of this research a community health worker is the same as the lay health worker.
Health Related Quality of Life (HQoL)	The HQoL is one of the measurements used in economics and can be defined as "how well a person functions in their life and his or her perceived wellbeing in physical, mental, and social domains of health over time" (Centers for Disease Control and Prevention (CDC), 2018) . However, the most commonly used outcome measures in health economics are aggregate measures that combine quality and quantity of life into a single measure. Examples of these are disability-adjusted life years (DALYs) and quality adjusted life years (QALYs) metrics.
DALYS and QALYs	DALYs are a combination of years of life lived in the state of disability (YLDs) and years of life lost due to premature mortality (YLLs). QALYs, on the other hand, adjusts the health benefits (i.e. length of life) to reflect the HRQoL of the person during that time (Centers for Disease Control and Prevention (CDC), 2000).
Multimorbidity	The coexistence of multiple conditions in an individual (van den Akker et al., 1996)

1. Chapter One: Introduction

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1.1 Introduction

The health workforce plays an integral part in the health system. Without it, there will be no delivery of essential health services which may result in failed health care systems and poor health for the population (Mahlathini & Dlamini, 2015). Globally, the health care system faces challenges with shortages in health personnel (World Health Organization, 2016). As it stands, half of the countries in the world have the required number of health workers to achieve quality health care (Shobana Kamineni, 2019). This is also coupled by global health distribution inequities where countries like America account for 10% of the global burden of disease with 37% of the global health workforce whilst Africa accounts for 24% of the global disease burden with only 3% of the global health workers (Shobana Kamineni, 2019). According to the Global Health Workforce statistics, Africa has the lowest density of health workforce per 10 000 population as depicted in figure 1.1 below (The Global Health Observatory, 2021):

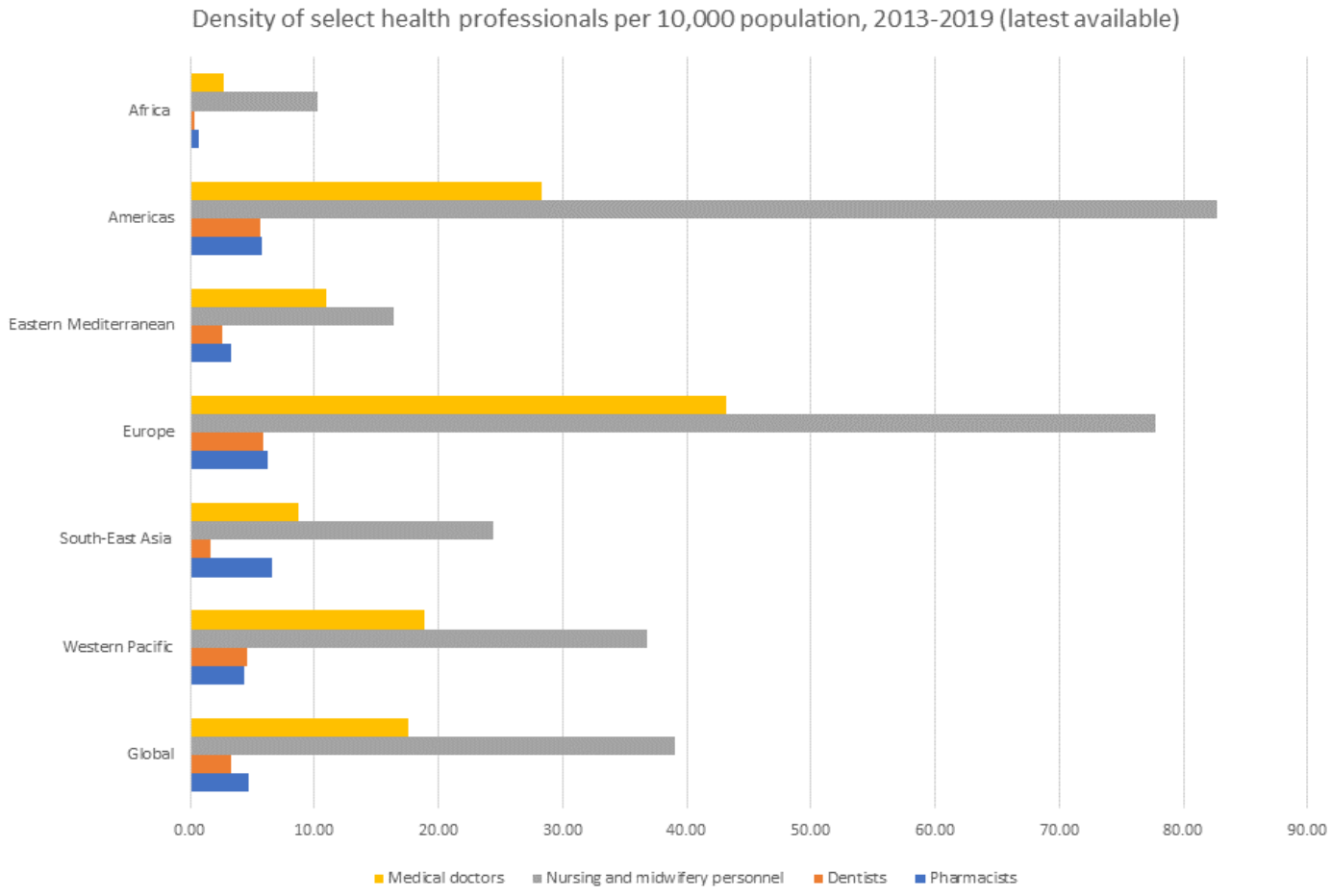


Figure 1.1: Graph depicting the health workforce density per 10 000 population among six continents relative to the global average ratios

Source: The Global Health Observatory, 2021

Sub-Saharan Africa (SSA) faces a critical shortage of health care personnel with 2 doctors per 10 000 population and eleven nursing/midwifery personnel per 10 000 (Naicker et al., 2010). In SSA more than 60% of the countries have extreme shortages of human resources for health (Campbell et al., 2013). South Africa currently sits at a physician density ratio of 7.6 per 10 000 population (Campbell et al., 2013).The rural areas of the country, which is home to 43,6% of the population, is served by only 12% of the doctors and 19% of nurses (South African Department of Health, 2011b).

The surge in NCDs in South Africa is placing a further strain on human resource capacity to deal with multiple disease burden. This is particularly evident in rural areas where acute infections are still prevalent and multimorbidity (due to chronic NCDs and ageing) is being increasingly reported. Currently, primary healthcare facilities have been dedicated as areas for treatment and management of NCDs (Coleman et al., 1998). However, NCD care in primary healthcare facilities in rural areas is still not up to an expected quality (Bresick et al., 2019). The poor management of NCDs has been partly attributed to shortage of health personnel in clinics (Tsolekile et al., 2015). For example, inadequate nurse/patient ratios tend to put immense pressure on the nurses who are constantly dissatisfied and thereof experience burn-out syndrome (Shah et al., 2021).

Health worker shortage exacerbate inequities in access to health care services and in health outcomes. A study by Chen et al (2006) shows that there's a positive correlation between the density of doctors and positive health outcomes in cardiovascular diseases. Ultimately, health workers are the most important players in delivery of health and improvement of health outcomes. The primary intent of health workers is to provide care to improve health (Chen et al., 2006). Therefore, without the right numbers of employed and trained health workers, people will not have access to care (O'Brien & Gostin, 2011).

To improve care for people with chronic communicable and non-communicable diseases, in the year 2011, the South African government introduced the ICDM as one of the healthcare reforms. The model aimed to improve operational efficiency in primary healthcare facilities. As this was a nurse-led initiative, this meant that nurses had to take on additional tasks like scheduling appointments, defaulter tracing and prepacking medications for

patients. Nurses, however, struggled to handle the additional workload which then affected quality of health care (Mahomed et al., 2014).

As part of reorientation of services to support the Integrated Chronic Disease Model (ICDM), the Nkateko trial implemented a lay health worker intervention, in rural Mpumalanga, which aimed to improve the hypertension health outcomes through task shifting (re-organisation of health services) from the nurses to lay health workers. This research report reports on the cost consequence analysis of the Nkateko trial.

The rest of the introductory chapter provides a review of available literature focusing on the impact and the associated costs of hypertension management interventions in low-middle income countries, particularly in South Africa and in some of the high-income countries. It first starts by providing the background information on the primary health care system in South Africa and a brief description of how it is currently standing since the country transitioned to a democratic state. It then provides a review of relevant literature which first looks at the burden of hypertension. The literature further explores the hypertension impact (individual, heath system and macroeconomic), interventions introduced in South Africa and the use of lay health workers. This chapter ends by providing the problem statement, justification of the study and finally the research question, aim and objectives.

1.2 Background: The South African health system

Before introducing the reader to the subject matter of hypertension management in South Africa, it is important to start off by understanding the South African health care system. This section introduces the reader to a brief description of the South African health care system, its link to the current primary healthcare system post-apartheid and ends-off with a brief description of primary healthcare reforms.

The South African health care system is divided into two: public and private health care system. The public health system caters for 84% of the South African health population whilst the private sector caters for 16% of the population (McKenzie et al., 2017). The distribution of health workers in South Africa is uneven, public health facilities only account for 30% of the workforce with 70% in the private sector (South African Department of

Health, 2011a). Rural areas have substantially less access to health personnel especially qualified or skilled health professionals compared to urban areas (Zeelie, 2014).

The disproportionality in the provision of health care services is further exacerbated by the income inequality that exists, resulting in the high-income earners favouring private health care (Maillacheruvu & Mcduff, 2014). A report in 2015 highlighted that the rich quintile had 6% of the health needs and received 35% of the health benefits, whilst the poor quintile has 25% of health needs while receiving 13% of health benefits (McKenzie et al., 2017). Tudor Hart (1971) dubbed this as an inverse care law, "the availability of good medical care tends to vary inversely with the need for it in the population served." Besides the healthcare personnel shortage, other current public health sector challenges include: poor management, poor care delivery systems and not enough spending on health (Gheorghe et al., 2018).

The public sector is divided into primary, secondary and tertiary care with majority of individuals accessing care via public primary care (Mahlathini & Dlamini, 2015). Primary Health Care (PHC) in South Africa, like in other countries, has been introduced as the first point of contact in the health system. Considering the public health care system failures from the apartheid regime, efforts have been placed to improve and strengthen the public health care system. The first elected democratic government introduced primary health care as one of the health restructuring programs to help address the health and social inequalities (Maillacheruvu & Mcduff (2014) and African National Congress (South Africa) et al. (1994)). The then government wanted to "improve access to health care for the poorest and most marginalised" (Burger & Christian, 2020).

Twenty-six years later, after South Africa gained its democracy, and after the release of the National Health Plan, there are still significant problems in the public health sector, especially primary health care facilities.

Interventions South Africa has introduced: ICDM and the Ideal Clinic

To help improve the primary health care landscape, South Africa introduced some reforms as depicted in Figure 1.2 below adapted from McKenzie et al., (2017). The figure provides a breakdown of the reforms that have taken place between the years 1994 till 2015. These include, for instance, the ICDM and Ideal Clinic.

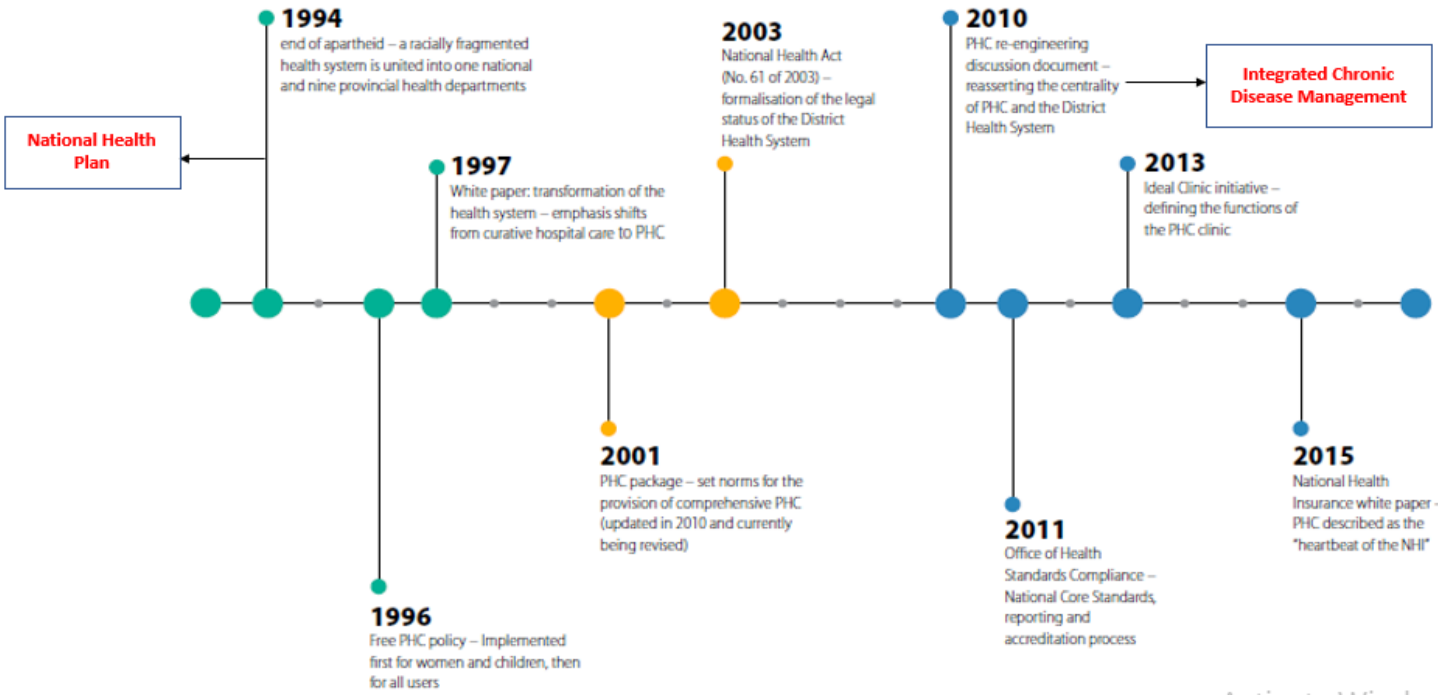


Figure 1.2: Summary of the Primary Health Care reforms that have taken place in South Africa since the year 1994.

Source: McKenzie et al., 2017

a) ICDM model of chronic disease care implementation in South African Primary Health care facilities

In 2002, the World Health Organization (WHO) realized the need to address chronic conditions by introducing a model called an Innovative Care for Chronic Conditions (ICCC). This was introduced for countries to use to improve chronic disease management. This framework recognized the need for an integrated model of care (Pruitt et al., 2002).

The South Africa National Department of Health (NDoH) then adopted the ICCC framework to develop the ICDM model of care as a method to improve chronic disease management at the level of primary health care facilities (Mahomed et al., 2014). This also forms part of the re-engineering of PHC systems in South Africa. The ICDM model is "a model of managed care that provides for integrated treatment, prevention and care of chronic patients at the PHC level to ensure a smooth and continuous change to assisted self-management within the community" (Asmall & Mahomed, 2013). The ICDM aims to improve the quality of chronic disease management and to ensure the best health outcomes for individuals with chronic NCDs and communicable diseases (Ameh

et al., 2016). This model aimed to respond to the increasing burden of disease in a cost-effective and efficient way (Mahomed et al., 2014).

The ICDM consists of three inter-related levels namely: health facility level, community and population level. These focus on the outcomes of "improved operational efficiency and quality of care; individual responsibility and informed population", respectively (Mahomed et al., 2014). As part of the health facility-level intervention, the ICDM focused on facility reorganization. The model focused on reducing patient waiting times and patient load to improve patient process flows. This was to be achieved through having designated service areas, task-sharing, patient appointment scheduling and tracking (Mahomed et al., 2014). However, difficulties were experienced due to "inadequate and inappropriate facility infrastructure" i.e. shortage of space in the facilities (J. R. Hunter et al., 2017). It also resulted in nurses facing an additional burden in their daily tasks which included managing appointment scheduling, preparation of medication packages and management of queues for chronic disease patients, thus adversely affecting the execution of the ICDM model (Limbani et al., 2019).

b) The ideal clinic

To assess and monitor the quality of health services in primary health care facilities, the National Department of Health (NDoH) implemented an Ideal clinic program in the year 2015. The ideal clinic program is the core of primary health care strengthening. Quality health services, as defined by the NDoH, are services that provide short waiting times, good positive attitudes from staff, clean facilities, prioritizes patients' security and safety (McKenzie et al., 2017). An ideal clinic is defined as a clinic with "good infrastructure, adequate staff, medicine and supplies, and good administrative services". The ICDM model formed a key focus area within an Ideal Clinic (McKenzie et al., 2017). In preparing the country towards universal health coverage, the Ideal Clinic has become important to address quality standards in primary health care facilities.

As part of reorientation of services to support the Integrated Chronic Disease Model (ICDM), the Nkateko trial implemented a lay health worker intervention, in rural Mpumalanga, which aimed to improve the hypertension health outcomes through task shifting (re-organisation of health services) from the nurses to lay health workers. This paper reports on the cost and consequences associated with using lay health workers to improve

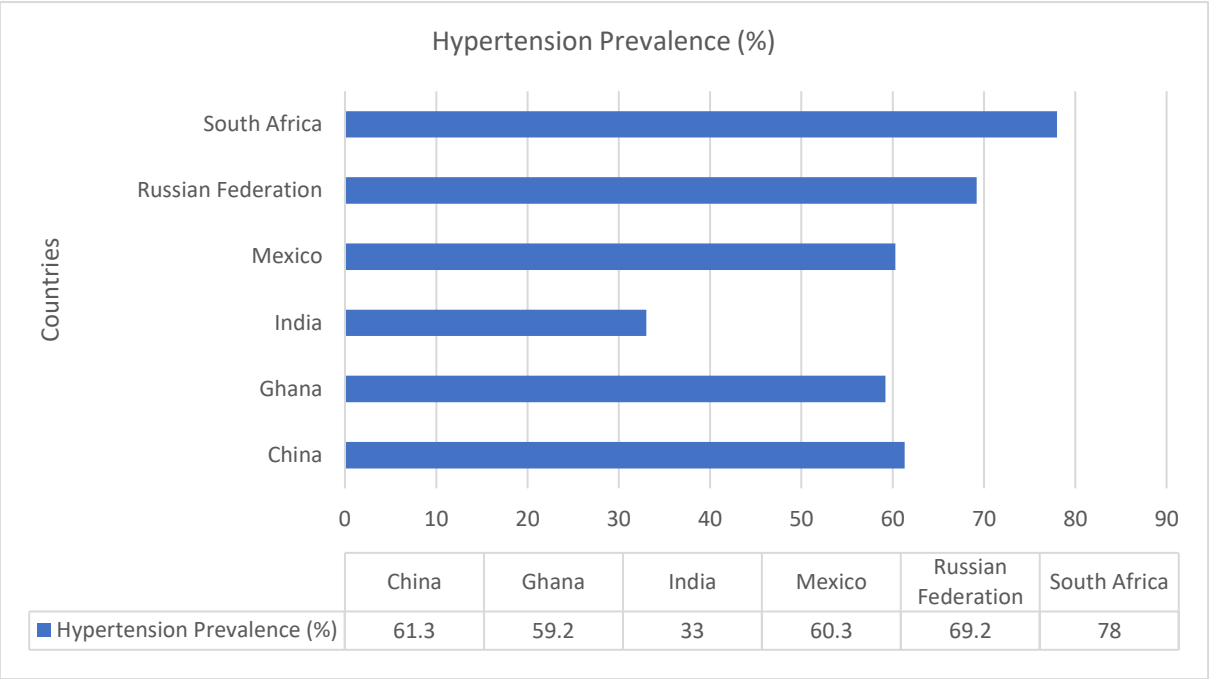
management of hypertension in rural South Africa within the Nkateko Randomized Controlled Trial (RCT). This research report is a sub-study to the Nkateko Randomized Control Trial. A detailed description of the trial is provided in chapter two of this research report.

1.3 Literature Review

1.3.1 The severity of the hypertension problem

Hypertension is the highest cause of death in the cardiovascular group and accounts for an estimated 9 million global deaths annually. Hypertension, a “silent killer”, has a huge impact globally due to its prevalence, incidence and high mortality rates. It has been dubbed the “silent killer” due to its asymptomatic presentation (Mpe, 2015). It falls under the category of chronic noncommunicable diseases (NCDs). Chronic diseases, as defined by the WHO, are a group of diseases that last long-term and require long-term treatment and on the other hand, non-communicable diseases are a group of diseases that are non-infectious and cannot be passed on from person-to-person (Ameh et al., 2016). A patient is said to have hypertension if their blood pressure (BP) is more than 140mmHg systolic BP and greater than 90mmHg diastolic BP, and when a patient is on antihypertensive medication (Seedat et al., 2014).

Hypertension continues to rise globally and locally. A paper by Zhou et al (2021) found that hypertension currently affects 32% of the adult population (that is individuals between the ages 30 -79 years old) in the world. Looking at the global scale, Mexico, Ghana, South Africa, China, Russia and India have the highest number of hypertension rates with South Africa taking the lead as depicted below in figure 1.3 (Ameh et al., 2016).



	China	Ghana	India	Mexico	Russian Federation	South Africa
Hypertension Prevalence (%)	61.3	59.2	33	60.3	69.2	78

Figure 1.3: Bar graph showing the differences in the hypertension prevalence rates between the six countries, amongst adult population (aged 50 and above).

Source: Wu et al., 2015

A study that was conducted in the Sub-Saharan region (South Africa, Tanzania, Uganda, and Nigeria) indicated that a large number (approximately 50%) of their participants were not aware that they had hypertension. For those participants who knew their hypertension status, 50% of them had uncontrolled hypertension (Guwatudde et al., 2015).

South Africa currently faces a quadruple burden of disease namely: NCDs, HIV/ AIDS and tuberculosis, maternal and child mortality, and injury and violence which continue to place a huge strain on the public health service (Dookie & Singh, 2012). HIV/AIDS and NCDs account for the highest-burden in the country (Ameh et al., 2016).

Amongst the group of NCDs, cardiovascular diseases (CVD) are the major contributors to the NCD burden. In the year 2016, NCDs accounted for approximately 51% of all deaths in South Africa, 19% of that was due to CVD (World Health Organisation, 2018).

In South Africa, hypertension affects around 4.4 million people (Cairncross et al., 2017). In rural South Africa, hypertension prevalence continues to rise and as a result stroke prevalence- due to a lack of management of

hypertension- continue to rise. Based on 2016 data, no less than 30,000 strokes occur annually in rural South Africa (Maredza & Chola, 2016). This is the case in rural Mpumalanga where there is a high prevalence (41%) of NCDs, especially self-reported hypertension cases in the age group 50 years and above (Ameh et al., 2016).

Current evidence suggests that there is poor detection, a low proportion of individuals are aware of their hypertension status and inadequate monitoring of the disease (that is, less than 1 in 5 people with hypertension have it under control) (Ataklte et al., 2015).

1.3.2 Assessing the economic impact of hypertension and related interventions in South Africa and other countries

1.3.2.1 Microeconomic Impact at the level of the individual

The microeconomic impact examines the economic consequences at the level of the individual and the household, focusing on the financial and health burden (resulting from untreated hypertension) and gains (resulting from treated hypertension). Managing hypertension carries several health benefits for the individual and society. Those benefits range from improved health-related quality of life (HRQoL), deaths averted, and cost savings from improved HRQoL.

The long-term economic benefits of treating hypertension are well established from a societal perspective and arise from several factors including improved productivity. A US study showed that treating hypertension would lead to productivity gains of more than $11 billion (R161.8 billion), which would offset the $15.8 billion (R232.3 billion) in patient time costs as well as decrease “the number of people with uncontrolled hypertension by 4.7 million” (Dehmer et al., 2016). It would also reduce cardiovascular disease-related deaths by 165 000. This study simulated a 10year team-based hypertension care intervention that provided care to hypertensive patients who were treated but had uncontrolled hypertension. Team-based hypertension care is a team of social workers, pharmacists, nurses, lay health workers and dieticians. They assisted in medication management, conducting follow-ups, providing self-management support, and adherence (Dehmer et al., 2016).

Improved quality of life means that an individual will be able to work or provide for their family – this means income gained from work due to good health. As previously established, diseases like strokes and myocardial

infarctions, that result from untreated hypertension, have high economic costs (Maredza & Chola, 2016). Therefore, improved hypertension control could generate large cost-savings over time for both the individual and the health system. Paradoxically, the process of seeking hypertension treatment could be costly for several reasons.

Hypertension, like any other NCDs, exposes families to the financial burden which may result in individuals not seeking the right health care or treatment. In rural areas majority of families come from low income households who cannot afford the costs of care (Kankeu et al., 2013). They have to decide how to spend their limited time and funds. Families affected by NCDs like hypertension bear indirect costs due to their conditions. Indirect costs affecting both patient and carer can be the (i) time lost from work which becomes income lost and (ii) productivity loss. This therefore translates to a trade-off between seeking care now and losing money, or being faced with a disability later because you haven't sought care (thus not receiving any income later). Income loss also applies to their caretakers as they will have to spend time looking after them. According to Kankeu *et al* (2013), income loss for the patients form the highest percentage of indirect costs. Repeated visits to health facilities are usually a requirement for the treatment of NCDs due to the poor health of the patients. These repetitive visits will result in additional time loss from work for both the caretakers and patients.

Lay health workers have been associated with assisting with reducing waiting times in clinics and improved patient attendance in these facilities. This can, therefore, help reduce the impact on the society by allowing patients to seek care without compromising much of their work time and therefore result in more attendance which may result in improved hypertension management – which may lead to better health outcomes (Daviaud et al., 2018). To help summarize this, the diagram below derived from (Kankeu et al., 2013) provides a good summary of the microeconomic impact of NCDs (on households).

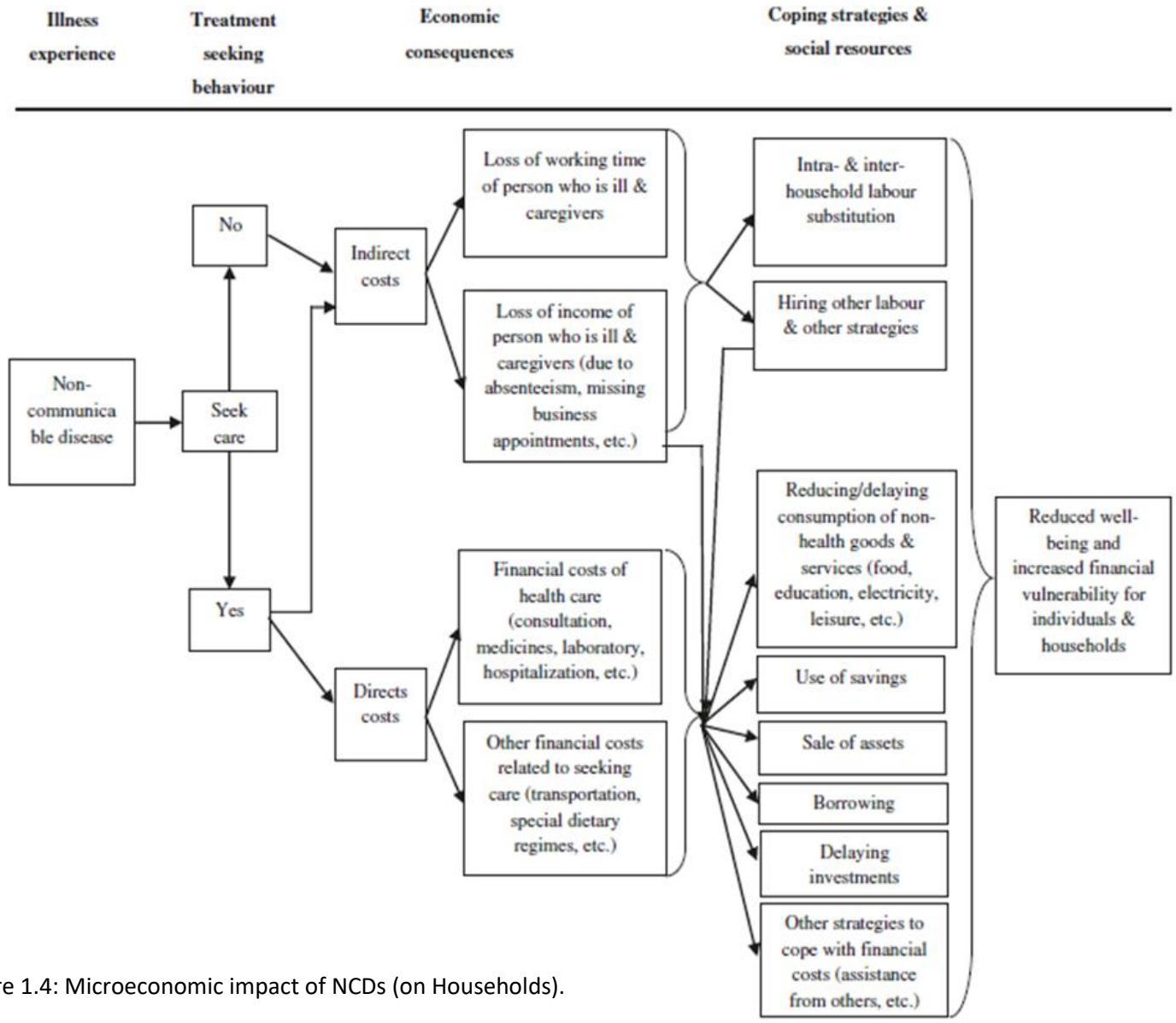


Figure 1.4: Microeconomic impact of NCDs (on Households).

Source: Kankeu et al., 2013

1.3.2.2 Health Sector Impact

Health sector impact focuses on the impact of the burden of disease in health facilities and health spending. A health sector impact provides insight on the program costs, direct healthcare cost and the associated impact resulting from treated and untreated hypertension (Zhang et al., 2017). According to the South African 2020/2021 health budget estimates, R25.18 billion has been allocated to treat communicable and non-communicable diseases. However, 99% of the budget is allocated to the treatment of HIV&AIDS and STIs and only 0.45% of the budget is allocated to treating NCDs (National Treasury Republic of South Africa, 2020). Due to the health budget constraints, careful considerations need to be placed towards interventions that can be

cost-effective. Hypertension and its sequelae (i.e. CVDs) are associated with high costs for the health sector (Hongoro, 2017). Although there is still limited data evaluating the cost-effectiveness of interventions geared towards hypertension management, particularly those using lay health workers, evidence suggests that lay health workers can be useful in assisting with the management of hypertension (He et al., 2017). In addition to that, the use of lay health workers has also been linked with addressing the shortages of health personnel, particularly in low-middle income countries (Rifkin, 2016).

A study using a 10 year life course model (using the South African uninsured population) of the use of community-based lay health workers resulted in the following benefits: (i) 10% increase in case-finding/treatment coverage; (ii) should there be at least two home-visits conducted by lay health workers over the 10 years to patients with uncontrolled hypertension, they can avert 14 266 DALYs; and (iii) given that lay health workers spend around 10% of their time focusing on hypertensive patients, the cost per DALY averted will be R105 051.

Managing chronic conditions like hypertension reduces the cost that the burden of disease imposes in the health system. Hypertension cannot be cured but can be managed, which therefore makes it important to understand the different types of treatments that exist and their costs to better understand the financial burden generated by the disease. Hypertension can come as a comorbidity to lifestyle diseases like obesity and other diseases like diabetes. Untreated hypertension results in a myriad of other diseases like stroke, kidney failure, myocardial infarctions, and cardiac arrests (Guwatudde et al., 2015). As a result, these subsequently cause an additional stress in the already overburdened health care system in terms of the number of people who will need treatment.

Management of these conditions require more health care resources, including specialised health personnel and costly treatments. Thus affecting healthcare expenditure, putting a strain in the human resources for health and the health care infrastructure (Ameh et al., 2016). Take stroke for instance, hypertension is a precursor to and a high-risk factor for stroke (U.S. Department of Health and Human Services, 2020). In rural South Africa, at least 30,000 strokes occur in a year and has high economic costs (Maredza & Chola, 2016). Therefore, by treating

hypertension which is considered as one of the modifiable risk factors to stroke, expenditure on stroke will be reduced. Treating the modifiable risk factors such as hypertension is considered to be effective (Boehme et al., 2017 and W. Johnson et al., 2016). Therefore, the main health system benefit of managing hypertension better is not only the reduced number of strokes, but also the reduced expenditure caring for stroke sufferers.

1.3.2.3 Macroeconomic Impact

When we speak of a macroeconomic impact, we are focusing on how the disease burden affects the country's economy mostly in terms of productivity in the workplace and the country's GDP. As discussed in the microeconomic impact section, hypertension has been linked to productivity loss as the risk of stroke and coronary heart disease that is attributable to hypertension is quite high. Stroke, for example, is associated with significant disabilities which affect the individual's ability to work. The inability to work affects the company which relies on the individual's set of skills. For individuals working in the informal sector, this will result in loss of income and loss of potential skills that could have subsequently been used in the formal sector. The informal sector coexists, or rather is linked with the formal sector as it "produces for, trades with, distributes for and provides services to the formal sector"(Chen et al., 2004). It is therefore important to assess the macro-economic impact of hypertension among workers in the informal sector.

It was estimated that between the years 2011 to 2015 the total economic loss due to CVDs in low-middle income countries was $3.7 trillion (R47.3 trillion), which represents close to "2% of GDP and half of the NCD economic burden across LMICs" (Gheorghe et al., 2018).

Using lay health workers has resulted in creating job opportunities for individuals which directly affects the country's GDP. Employment of such a cadre of workers in rural areas will stimulate rural economic growth as people will be receiving an income (Daviaud et al., 2018). Lay health workers are usually selected members of the community and are predominantly females. Therefore, by employing this group of individuals is likely to result in benefiting the children, household and the community they will be coming from, and because they come from the poorest families in rural areas- the benefit will be significant (Daviaud et al., 2018).

1.3.3 Use of lay health workers in the management of chronic diseases, especially hypertension

The use of lay health workers is associated with task shifting whereby tasks that have been conducted by health professionals are moved down to less qualified personnel like lay health workers. Interventions that use lay health workers for cardiovascular diseases prevention often focus on health screening and health education. Health education entails awareness of high blood pressure, cholesterol levels, and behavioural risk factors (Jacob et al., 2019).

The available research on the use of lay health workers suggests that using this group of personnel not only assist in improving operational efficiency but can be a cost-saving strategy, especially in low-middle income countries. Lay health workers earn relatively less income due to the lack of medical qualifications. They often rely on the training provided by the health facility or NGO they are working for. They are associated with improving the quality of care and health outcomes (Jacob et al., 2019).

A systematic review that was conducted by Seidman & Atun (2017) found that the use of lay health workers reduced the health costs for both the health system and the patients in 88% of the studies reviewed. The use of lay health workers also helps us address the health care personnel gap and failure to address this will continue to adversely affect the health outcomes (Zeelie, 2014).

A systematic review was conducted in the United States on the "*economic analysis of community health workers for chronic diseases (cardiovascular diseases and type-II diabetes mellitus)*". The analysis was based on individuals in the low socioeconomic status (SES) category and in most studies the patients received primary care. The systematic review found that "interventions using lay health workers are effective in preventing cardiovascular diseases and reducing healthcare costs (Jacob et al., 2019). In South Africa, there is limited research that has been conducted in analysing the cost-effectiveness of the use of lay health workers in primary health care facilities.

In the Nkateko trial, lay health workers were sending text-messages to the hypertensive patients to remind them of their clinic appointments. A study that assessed the cost-effectiveness of using a text-based messaging system to hypertensive patients found that the intervention was effective in improving patient's adherence to

medication and retention in care. Adherence in that study was assessed by medication re-fill rates and an improvement in systolic BP in the patients (Hongoro, 2017).

1.3.4 The cost drivers associated with deploying lay health workers to improve hypertension management, particularly adherence to clinic attendance in PHCs

The common cost drivers for lay health worker interventions are the salaries and benefits, training cost, and supervision. Other costs include the material used for education, health promotion, uniform, and overheads (Jacob et al., 2019). Often communication costs need to be factored in for lay health workers to contact patients. Depending on the facility, lay health workers also need a space to operate in.

While some projects use lay health workers on a volunteering basis, a cost analysis of the Strengthening Communities through Integrated Programming project (SCIP), found that including salaries for LHWs in their programs led to improved efficiency and outcomes, although this increased program costs (Bowser et al., 2015). SCIP is a USAID funded project that was implemented by Pathfinder International in Mozambique, Nampula province. The project had community health workers trained to deliver integrated health care services in the selected project districts in the Nampula province (Bowser et al., 2015). Other studies have corroborated this and concluded that remunerating lay health workers plays an important role in improving their motivation to work and retention (Nkonki et al., 2011).

1.4 Problem Statement and Justification

Hypertension is a high-risk factor for several diseases like heart diseases, strokes and kidney disease (Ataklte et al., 2015). Treatment and management of these conditions require more health care resources, including specialised health personnel and costly treatments. This affects healthcare expenditure and places a strain on an already overburdened health system (Ameh et al., 2016). Chronic care, particularly poorly managed chronic conditions, is considered the largest expense for health systems (World Health Organization, 2002).

Beyond its impact on the health system, hypertension has economic implications at both the micro-economic and macro-economic levels. Indirect costs of seeking care, such as travel costs, impose a significant economic burden on poor households whilst time taken off work and the consequent income loss is a reason for not

seeking care (Alonso et al., 2019 and Kankeu et al., 2013). In terms of the macroeconomic impact, a study by Asakura et al (2021) found that hypertension resulted in more than US$249 billion in lost GDP in Japan due to productivity losses. Thus, highlighting its substantial impact on the macroeconomy. This study created life table models to estimate years of life lost, total deaths and productivity adjusted-life years among hypertensive patients in Japan between the ages 24 -64 years, with a simulated follow-up to the age 65years (Asakura et al.,2021). With an increasing number of patients with chronic diseases, particularly hypertension, affordable and effective care becomes a priority (Mahomed et al., 2016)

Despite increased attention to NCDs and their risk factors, in South Africa funding commitments still prioritise HIV/AIDS. It has been reported that around 99% of the Minister of health/health treasury budget is given to treating and managing the HIV epidemic and yet little has been placed towards the treatment of NCDs and the functioning of District health system (DHS)[1] (National Treasury Republic of South Africa, 2020). The limited budget is a challenge as this may entail those interventions geared to improving hypertension will have limited funding which therefore calls for cost effective interventions in the interim and going forward.

Literature suggests that the use of lay health workers has been effective in improving chronic disease outcomes and the interventions were cost effective. However, there are no studies that evaluate the use of facility based lay health workers for the management of hypertension and evidence of their cost effectiveness is limited in South Africa. One study in South Africa conducted a costing analysis of a facility-based lay health worker but it was for the management of HIV & AIDS. At the community level of interaction of the ICDM ("assisted self-management" component), are the community health workers in ward-based a]outreach teams (Asmall & Mahomed, 2013). As a result, little is known about the costs of using lay health workers in facilities within the ICDM model. This highlights the gap and importance of doing further research in the field of identifying resource use and the costs associated with using facility based lay health workers for the management of hypertension and their impact on health outcomes.

[1] The DHS looks after the PHC facilities in each province.

This study will therefore provide costing analysis with its associated consequences of using a facility based lay health worker in clinics to improve hypertension management within the context of the ICDM and Nkateko Trial. The outcome of this study can be used as a guide for other rural primary healthcare clinics in South Africa.

1.5 Research Question, Aim and Objectives

1.5.1 Research Question

What are the costs and consequences of deploying lay health workers to improve hypertension management, particularly adherence to clinic attendance in primary healthcare clinics in Mpumalanga?

1.5.2 Aim of the Study

This study aims to estimate the financial costs and cost-consequences associated with using lay health workers to improve clinic attendance and attendance on scheduled appointments in resource-constrained health facilities.

1.5.3 Study Objectives

Objective 1

To determine costs associated with the deployment of lay health care workers in the Nkateko Trial (direct intervention/program costs) and consequences, to improve clinic attendance (through improving the process of care).

Objective 2

To present the mean and incremental costs and outcomes of the intervention as a cost-consequence analysis.

Objective 3

Conduct a literature search on the descriptive consequences (that is, the potential long-term health and other clinical benefits) and financial consequences (that is, estimate the potential savings and costs) that might result from increased attendance by patients with hypertension at the clinic, for the following:

I. Individual: This could include life-years gained (improved quality of life), due to the improved adherence to medication that results from improved attendance for care. This may result in potential productive years of work gained – therefore improved earning potential.

II. Health Systems: This could include, for instance, the strokes averted. Financial example are the reduced costs due to having fewer stroke patients. While the descriptive example is the reduced burden in health facilities

III. Macroeconomic: This could include additional workforce due to deaths averted and the potential growth in GDP that may result from added workforce

2. Chapter Two: Methods

2.1 Introduction

This section outlines the Nkateko trial, study design and presents a detailed description of the methodological approach used in the cost-consequence analysis. It starts by introducing the reader to a description of the Nkateko trial and its link to the current study. It is then followed by the description of the study site, population and sample used, data collection methods, data cleaning and analysis and the ethical considerations for the study. This chapter will enable the reader to understand how the researcher addressed the research question and aims of the study i.e., understanding the cost and consequences associated with deploying lay health workers to improve clinic attendance and attendance on scheduled dates.

2.2 Nkateko Trial and its link to the current study

The Nkateko Trial used a lay health worker intervention to improve hypertension management in hypertensive patients. The RCT was conducted in the Mpumalanga province, Bushbuckridge sub-district, to assess whether deploying lay health workers in the clinics would improve hypertension management, under the ICDM. It used seven different clinics and a community health center to assess this intervention. The intervention was designed to improve the flow of patients in the clinics and the patients' journey. However, nurses were inundated with extra tasks and struggled to manage them which affected the implementation of the model (as it was "not implemented as intended") (Limbani et al., 2019). The study hypothesised that under the new integrated care model, the lay health workers will manage to assist nurses with the educational and the administrative aspect of care whilst the nurses continue to focus on clinical aspects thus resulting in better health outcomes (Goudge et al., 2018).

Lay health workers received training from an experienced nurse who was the implementation manager. The implementation manager managed the four intervention clinics where each lay health worker was based. She was responsible for recruitment, training and supervision of the lay health workers. Lay health workers took over the additional tasks that were conducted by nurses in the intervention clinics. Lay health workers prepared patient files for their visits, controlled the vital signs station, scheduled appointments, provided counselling,

assisted in prepacking medication and conducted visit reminders (through calls or text messages) to patients with hypertension (Limbani et al., 2019).

The study was conducted over 18 months and had two arms:

a) Control Arm: These were clinics that continued with normal care processes i.e., no lay health worker was placed at their sites. These clinics had chronic (communicable and non-communicable) disease patients.
b) Intervention Arm: These were the clinics that had lay health workers. These clinics had chronic (communicable and non-communicable) disease patients. Patients in these clinics were divided into two groups
    i. Sub-group A: This group of patients, hypertensive patients, received clinic visit reminders through text messages and calls from the lay health workers throughout the course of the intervention.
    ii. Sub-group B: These were other patients who did not have hypertension. This group of patients did not receive any visit reminders from lay heath workers.

Process evaluation of the Nkateko Study

A process evaluation was conducted alongside the Nkateko trial to evaluate how the lay health worker intervention supported the ICDM model (Limbani et al., 2019). This was carried out in all the clinics (intervention and control) in four periods namely: preintervention phase, introductory phase, mid-way and end of intervention. Data was collected by data clerks recording the attendance and chronic condition of each attendee. The process evaluation concluded that the lay health worker intervention led to an increased number of patients attending the clinic and improved attendance by patients on their scheduled appointment day (Limbani et al., 2019). In this cost consequence study, we will assume that these outcomes indicate an improvement in management of hypertension due to the lay health workers, even if blood pressure itself did not have significant improvements.

The clinics did see improvements in the way the clinics were functioning, namely: reduced waiting times and increased clinic attendance. The main outcome that was to be assessed was the improvement in hypertension status and management assessed through population-based surveys. The study did see an improvement in blood pressure measurements; however, it was not significant enough to be considered a positive outcome of the study. The cost data and consequences identified and measured during the Nkateko Trial were used as data inputs for this economic evaluation. The results will be discussed in the results and discussion chapter.

2.3 Study design

The primary study was a cluster RCT with repeated cross-sectional surveys with two study arms. There were eight clinics, four were intervention clinics that had two lay health workers in each clinic and the other four control arm clinics were without lay health workers. Each of the eight clinics including the population it served, comprised a cluster (Goudge et al., 2018). The outcome measures of interest included evaluating the percentage change (before and after the intervention) in the high blood pressure (BP) measurements (Goudge et al., 2018).

Clinic attendance data was collected through observations of clinic activities during the process evaluation. During the process evaluation, an experienced data clerk collected identifying data (name, address, date of birth, cell phone number) in order to match each patient with the Health Demographic and Surveillance System (HDSS) database. The date of attendance and their expected next date of attendance was recorded for each patient as well as diagnosis (Goudge et al., 2018). Stratified random sample surveys were used to collect data on the changes of hypertension control and changes in the number of patients accessing treatment. These questionnaires were administered at baseline and end of intervention.

In this research report, a cost-consequence analysis was conducted using an expenditure method whereby financial records are used to estimate the costs of delivering the intervention. A cost-consequence analysis compares the costs of the intervention to its consequences (benefits/outcomes). This method of evaluation allows for an assessment of a multidisciplinary of outcomes (which are expressed in their natural units) and their related costs. This method does not use thresholds to define its effectiveness but gives the decision maker an opportunity to discover which intervention is effective based on the costs and outcomes presented (NICE, 2018).

Costs have been collected prospectively and were categorised into recurrent and capital costs, using South African Rands. Recurrent costs are costs assigned to items immediately consumed and need to be replenished. Capital costs are costs assigned to items that produce ongoing benefits over a long period. For this study this included lay health worker uniform and equipment. To help identify such costs an activity-based approach was used. Activity-based approach observes the type of activities taking place in the implementation phase of the intervention, grouping these activities in costing categories then identifying the cost/line items. This method of costing is also called an ingredients-based approach which multiplies the quantity of resources by their cost, in order to obtain total costs (Zeelie, 2014).

2.4 Study perspective and the assessments of related costs

The cost-consequence analysis was undertaken from the health provider's perspective. This type of perspective evaluates the costs incurred by the provider which include, for instance, training and recruitment costs for lay health workers. This study focused on the financial costs. Financial costs are similar to accounting costs, they look at the monetary value of actual inputs used to produce a good or service (Hongoro, 2017). These costs were further categorized into capital costs and recurrent costs.

2.5 Study Site

The primary study was conducted in Mpumalanga province, Bushbuckridge sub-district, South Africa (Goudge et al., 2018). This area is in a Health and Demographic Surveillance Site (HDSS) for Rural Public Health and Health Transitions Health Unit for Wits and the Medical Research Council (MRC) based in Bushbuckridge (Limbani et al., 2019). This site was developed in 1992 and was previously used for district health development and training of primary health care nurses. The area currently focuses on research/trials targeted at evaluating the causes and consequences of complex population, health and social transitions (Kahn et al., 2012).

2.6 Study Population and Sample

The primary study population were people with hypertension living in the catchment areas of the eight clinics included in the trial. In the primary study, the inclusion criteria for the clinics were for them to be located on the

study site. A 1:1 simple randomisation for clinics (intervention and control) was conducted in front of the clinic staff and the community (Goudge et al., 2018).

Target Population

The target population are the chronic disease patients, particularly adults with hypertension

Target Audience

The target audience are the health policy decision makers such as the Government Health ministries and District Health Managers.

2.7 Data collection, data cleaning and data assurance

Expenditure data, prospectively collected during the course of the trial (February 2014 to September 2015), formed the basis of the cost-consequence analysis. Data was provided by the administrator, who was responsible for recording expenditure data. Key to this data were salary costs, training costs, communication and travel costs. Throughout the data cleaning and analysis phase, information that was missing was requested from the administrator, HR administrator who was responsible for recruitment, implementation manager and the study coordinator. A data collection sheet was used to extract the cost data from the financial records provided by the trial researchers.

2.8 Methodological approach to costing and data analysis by study objective

2.7.1 Identification, measurement and valuation of direct intervention costs (Objective 1)

The cost-consequence analysis focused on a comprehensive assessment of the costs associated with delivering the Nkateko intervention. These were the costs that are linked to hypertension management in the intervention. The control arm of the study follows a do-nothing approach- where there were no lay health workers in the clinics and continued with normal standard of care. Since nothing essentially changed in control clinics, this was assumed to equal zero intervention costs. This means that this study measured the incremental costs associated with adding the lay health workers in clinics in the real world as the trial was a pragmatic RCT. Given that the costing perspective is that of the health provider and using a bottom-up costing approach, the following intervention costs were identified, measured and valued.

Intervention Costs

These were the direct intervention costs, which are the immediate costs incurred through the delivering of the intervention. Direct intervention costs included personnel costs (specifically lay heath workers who were deployed in the clinics and the implementation manager who provided oversight); communication costs for appointment/visit reminders; training costs for lay health workers; equipment used; stationery costs and transportation. Total costs were calculated and presented into two categories, capital and recurrent costs. The line items that make up the total capital and recurrent costs were calculated separately (in separate excel sheets) to determine the total costs per line item. These were calculated using the formula: quantity used multiplied by the unit cost.

The costs that attributable to the implementation manager were averaged out across all clinics as the manager provided oversight across all four clinics. The implementation manager in the study used a hired car during the course of the study. The hired vehicle costs used by the implementation manager were recorded as recurrent costs. Usually, maintenance is done by the hiring company. However, there were vehicle operating and maintenance costs that were captured in the trial and were used as part of the analysis.

Office equipment costs were annuitized using the amortisation method, at 3% discount rate (A. L. Creese et al., 1994). The lifespan/ working life years of the office desks and IT equipment were estimated to be 15 years and 3years, respectively. An amortisation method was used using the following variables: the cost of purchasing the equipment, working life years, annualization factor and discount rate. The following formula was used (A. L. Creese et al., 1994):

$$Annual\ Cost\ of\ equipment\ = \frac{Current\ Value}{Annualization\ factor}$$

The total costs of delivering the Lay health worker intervention were estimated separately for each clinic. These were presented in a graph and tables to show the differences in costs between clinics. In addition, the average (mean) cost per person was calculated. However, instead of calculating the average cost per person (using estimate of catchment population served by the clinics), the number of patients using the clinic per nurse was

used. This was calculated using the average number of visits per nurse per month. To calculate the average cost per additional visit per hypertensive patient (marginal cost), the difference in the number of hypertensive patients (before and after the intervention) was the number used to divide the total intervention cost of that period of the study. These costs were categorised into phases of the trial implementation: (i) start-up costs (material development and recruitment costs) and (ii) implementation costs (capital and recurrent costs).

2.7.2. Determining consequences (objective 1)

The consequences of the study were derived from the primary study. These included the outcomes that reflect clinic attendance.

The following are the core outcome variables:

- The increase in number of hypertension patients attending from the first month of the trial to the last month of the trial.
- The increase in the number hypertension patients attending on their appointment day (within 3 days of their appointed day) from the first month of the trial to the last month of the trial

Table 1: Cost variables included in the cost analysis by cost category

Cost component	Description	Source of data
	Start-up Costs	
Material development and training costs	• Initial Training of lay heath workers (Costs per training) • Training/education material • Building rental per session of training • Refreshments costs per training session • Intervention implementation workshops	Financial and administrative records
Recruitment activities	• A levy of 10% of total implementation costs	
	Capital Costs	
Office Equipment	• Use of office equipment by lay health workers on the vital signs station • Cost of office equipment per lay health worker and implementation manager	
Cell phones	• Cost per unit of cell phones used	

Recurrent Costs		
Vehicle	• Used by the implementation manager travelled to different clinics • Hired vehicle cost for Implementation manager	Expenditure records Financial and administrative records
Training	• Lay Health worker refresher training (cost per session, cost per lay health worker trained) • Number of trainings was be factored in • Refreshments costs	
Vehicle maintenance	• Maintenance costs of used vehicles, tyres • Costs of fuel per month	Estimates from literature (Local dealer estimates will be used)
Transport operating costs	• Transportation costs (Lay health workers reimbursed for travel with local transport	Financial and administrative records
Consumables	• Airtime per month • Stationery costs	
Outcome variables		
Improved clinic attendance	• The increase in the number of hypertensive patients clinic visits per month between the start of the trial and the end	Data were collected by study data clerks placed in the clinics for the period May 2014 to July 2015.
Improved attendance on scheduled appointments	• The increase in the proportion of patients with hypertension that attended their appointment on their actual appointment dates, between the start of the trial and the end.	
Analysis variables	**Description**	
Costs	• Mean costs of the intervention per intervention clinic • Incremental costs of the lay health worker intervention	Total costs calculated as part of this economic evaluation
Consequences	• Identified study outcomes as reported in the trial: Changes in clinic attendance • Descriptive consequences: Description of the benefits of improved clinic attendance of the hypertensive patients, strokes averted and other societal benefits like improved productivity • Financial consequences: Description of the potential savings and costs for the health and the economic impact	Primary study and external literature

2.7.3 Overall summary of analysis - combining costs and consequences (Objective 2)

The mean costs were calculated using simple descriptive statistics using excel. The incremental cost is the total cost of the intervention. These costs were summarised and presented against the selected outcomes of the trial in a cost-consequences table. The table also included the financial and descriptive consequences. Final costs were presented in 2015 prices. The following inflation rate calculation was used to inflate costs:

$$Total\ Cost_{(2015\ price)} = Cost_{(x\ year)}(1 + Inflation\ rate)^{n}$$

Whereby:

i. Total cost is the inflated cost to reflect 2015 prices
ii. Cost is the current cost for the year- the cost that you want to inflate, and x is the year in which the cost is presented in
iii. Inflation rate for the year you are inflating to
iv. N is the number of years

2.7.4 Measurement and valuation of financial consequences and identifying descriptive consequences (Objective 3)

A literature search to gather data on financial and descriptive consequences was conducted, using recent research papers and publications from the period 2000 to 2020 as reports from international organisations like WHO were searched that pre-dated the timeframe as detailed information had been provided in these earlier reports. Studies were included if they met the following criteria: in the South African context and in English, research papers with published materials from low-middle income countries. PubMed and Google Scholar were consulted for open access papers. Other databases searched included the South African government's national treasury website (to get information on health care expenditure including budget allocation to primary healthcare clinics and allocation for non-communicable diseases), South African department of health website and the WHO. In addition, a general web search was conducted. Data from Peer reviewed articles, systematic reviews and economic evaluations were prioritised in determining descriptive consequences. Search terms are

stated below under the description of the descriptive and financial consequences headings. Filters were used to narrow down searches into papers that look at hypertension patients who are in the age group of 18 years and above. Costs from other low-middle income countries were converted to South African Rands (ZAR) using currency conversion rates for that given year.

Descriptive consequences included data that discussed the likely effects of the intervention on the society. This involved supplementing data from the current study with externally published data, for example, on long-term cost-effectiveness of alternative approaches to hypertension care and management. Information was drawn from supplementary data as it was beyond the scope of this study to model the hypertension disease pathways to help explain long term health effects. Data collected represented, for instance, loss of life years due to uncontrolled hypertension; number of strokes averted per 100 000 population; hypertension management leading to prevention of premature deaths (40 per 1000 people) (Alcocer & Cueto, 2008). Search phrases included: “strokes averted”; “life years gained”; “improved quality of life”; “hypertension management health benefits” (other studies referred to hypertension as high blood pressure) and “productive years of work” followed by terms like treatment of hypertension. Other literature focussed on productivity losses and loss of earnings as a result of work absences due to care-taking (Daviaud et al., 2018).

To estimate potential long-term financial consequences supplementary data was again drawn from literature. Search terms included: “hypertension economics”; “costs of treating strokes”; “non-communicable diseases”; “NCDs budget allocation” (this will help assess willingness to pay); “cost per missed appointment” and ((‘non-attendance’ OR ‘defaulted’ OR ‘no show’) AND (‘appointment’ OR ‘follow-up’) AND (‘hypertension’ OR ‘high blood pressure’) AND (‘family practice’ OR ‘clinic’) AND (‘economic cost’ OR ‘cost-saving’ OR ‘costs’)). Due to the time restrictions for completing this research a traditional literature review (not a systematic review) was conducted to understand the potential financial and descriptive consequences (objective 2). The traditional literature review is not as rigorous as a systematic review therefore it has a potential to miss other studies. However, to address that limitation a few people who have previously done this work were consulted and advised on other sources of information. Furthermore, reference lists of the relevant identified studies were looked at for any other papers that may have been missed by the basic search. Reviewed literature on the

consequences was categorised into the objective's themes and presented in a table format using the approach recommended in a National Institute for Care and Clinical Excellence (NICE) guidance document (Rtveladze et al., 2016). The search list of the databases and search terms used is reported in appendix two.

2.8 Ethical considerations

Note that the ethical and legal issues pertaining to this study are limited. Ethics approval was obtained from the University of the Witwatersrand (Clearance certificate number M200703) through the Human Research Ethics Committee (HREC) (Medical). This process of approval took approximately 2months. The data that was used is sourced from the primary study (Nkateko trial) and has already been collected. The primary study had also obtained ethics clearance (M130964) from the University of the Witwatersrand, HREC (Medical). The ethics waiver letter is attached on the appendices for the purposes of examination. As the secondary study uses expenditure data, it therefore does not pose any harm to the subjects that have been used. Data is securely stored in password protected format and saved in the research laptop, and back-up was through the students account Microsoft One drive which is also password protected.

3. Chapter three: Results

3.1 Introduction

This chapter focuses on the results that were generated in the study using the expenditure data from the Nkateko trial. The results are divided into the three objectives which the results aim to answer. Objective 1 presents the costs in the following manner: (i) results of start-up costs (table 2); (ii) results of capital costs; (iii) results of recurrent costs and (iv) total intervention costs (table 4). These costs will be presented to reflect total costs per intervention clinic in graphical and tabular formats. The costs will also reflect resources used during the course of the intervention. Other costs calculated are the average cost per month (table 5) and costs per patient (table 7). Lastly, Objectives 2 and 3 are presented in Table 8 provide a summary table to reflect results of the cost consequence analysis which will include the costs of the intervention together with the financial and descriptive consequences resulting from the use of the lay health worker intervention.

3.2 Results

3.2.1 Measurement and valuation of direct intervention costs (Objective 1)

The following period was used for cost analysis, Year 1 (February 2014 – January 2015) and Year 2 (February 2015 – September 2015). Note that year 2 of the intervention is made up of costs gathered for 8 months.

Start-up Costs

Start-up costs reflect costs from the period of February 2014 to April 2014. In this period there was recruitment of staff and the training of the lay health workers. The total start-up costs were R142 279.05 and comprised 10.9% of the total intervention costs. The table 2 below shows the breakdown of the start-up cost per clinic:

Table 2: Start-up cost per health facility (ZAR, 2015)

	Health Facility Name				
Item	**Troy**	**Orange**	**Timber**	**Hillard**	**Total**
Start-up Costs					
Total Start-Up Costs	**R36,104.02**	**R35,659.89**	**R35,304.59**	**R35,210.54**	**R142,279.05**

The costs across the intervention clinics are relatively similar due to the fact that each clinic employed two lay health workers and they all had the same training before being placed in their working clinic. Therefore, the materials used would be the same and the training will be the same. What will possibly explain the differences will be the refreshments that were provided on the day of training.

Capital Costs

Capital costs comprised the following: lay health worker uniform and cell phone costs, and the office equipment across all four clinics. Total capital costs for the period of 2 years in the intervention amounted to R17 770.82. This makes up about 1.4% of the total intervention costs as depicted in figure 3.1 below. In the first year of the intervention R11 541.92 was spent and in the second year R6 288.90 was spent.

Recurrent Costs

Recurrent costs comprised of the following: Vehicle (hired vehicle cost), personnel costs (lay health workers and implementation manager), training costs, transport operating costs, consumables, stationery, clinic repairs and maintenance, rent, vehicle operation and maintenance, and security costs. Recurrent costs make up 87.9% (R1 148 555.37) of the total intervention costs. The bulk of the recurrent costs come from personnel cost which make up 60% (R692 398.63) of the recurrent costs. Personnel costs are divided into the personnel costs of the lay health workers and implementation manager. Lay health workers salaries made up 50% of the personnel costs whilst the implementation manager comprised 50% of personnel costs. There were only eight lay health workers (two per clinic) and one implementation manager who was responsible to manage all four clinics.

Table 3:Presentation of Total costs by category per clinic in the two-year period (ZAR, 2015)

	Health facility			
Item	**Troy**	**Orange**	**Timber**	**Hillard**
Capital Costs (Operational Costs)	**Total**	**Total**	**Total**	**Total**
Cell phones and Lay Health Worker Uniforms	R1,635.48	R1,635.48	R1,635.48	R1,635.48
Office Equipment	R2,738.70	R3,012.78	R2,738.70	R2,738.70
Total Capital Costs	R4,374.18	R4,648.27	R4,374.18	R4,374.18
Recurrent Costs				
Vehicle (Hired vehicle cost)	R27,415.98	R27,415.98	R27,415.98	R27,415.98
Personnel (Lay Health workers	R83,631.61	R85,937.73	R87,865.32	R91,507.17
Personnel (Implementation Manager)	R85,864.28	R85,864.28	R85,864.28	R85,864.28
Training	R1,370.00	R1,370.00	R1,370.00	R2,185.10
Transport Operating Costs	R2,130.14	R2,130.14	R2,130.14	R2,130.14
Consumables (airtime)	R3,450.15	R3,450.15	R3,450.15	R3,450.15
Stationery	R166.75	R166.75	R166.75	R166.75
Repairs and Maintenance	R356.63	R381.62	R356.63	R356.63
Rent	R50,715.00	R50,715.00	R50,715.00	R50,715.00
Security	R25,357.50	R25,357.50	R25,357.50	R25,357.50
Vehicle Operation and Maintenance	R2,866.93	R2,866.93	R2,866.93	R2,866.93
Total Recurrent Costs	R283,324.97	R285,656.08	R287,558.68	R292,015.64

There were minor variations in the clinics for the following items: office equipment, training and lay health workers salaries'. There were extra desks (two) that were bought at the Orange clinic which explains the differences in equipment costs. In terms of training, there was a LHW training held at Hillard in the first year that was reported. When it comes to personnel costs for the lay health workers the following account for the variations:

(i) For the second year of intervention, July 2015, one LHW in the Hillard clinic was paid more (R1418.36 extra) than usual pay and more than the other LHW. This however is an anomaly.

(ii) There were differences in the months in which the LHW started working. LHW from Troy working in May 2014; Orange and Timber started in April 2014 and Hillard in March. This affected the total cost for the LHW salaries at the end of intervention.

(iii) Finally, there were differences in the first month's salaries for the LHW. When the LHW from Troy started working they earned more (R1627.94 difference) than the other LHW's (just for the first month of work). Afterwards they all earned the same. The same applied to Timber (R1302.06 difference) for the first month of April.

Total Intervention costs

The total cost of the intervention was R1 308 605.24 for the period February 2014 to September 2015. Table 4 together with figure 3.1 provide a breakdown of the total intervention costs per clinic.

Table 4: Total Intervention cost per clinic (ZAR, 2015)

	Name of Clinic			
Years	**Troy**	**Orange**	**Timber**	**Hillard**
Year 1	R214,769.85	R216,771.90	R218,204.14	R221,118.08
Year 2	R109,033.32	R109,192.34	R109,033.32	R110,482.28
Total	R323,803.17	R325,964.24	R327,237.46	R331,600.36

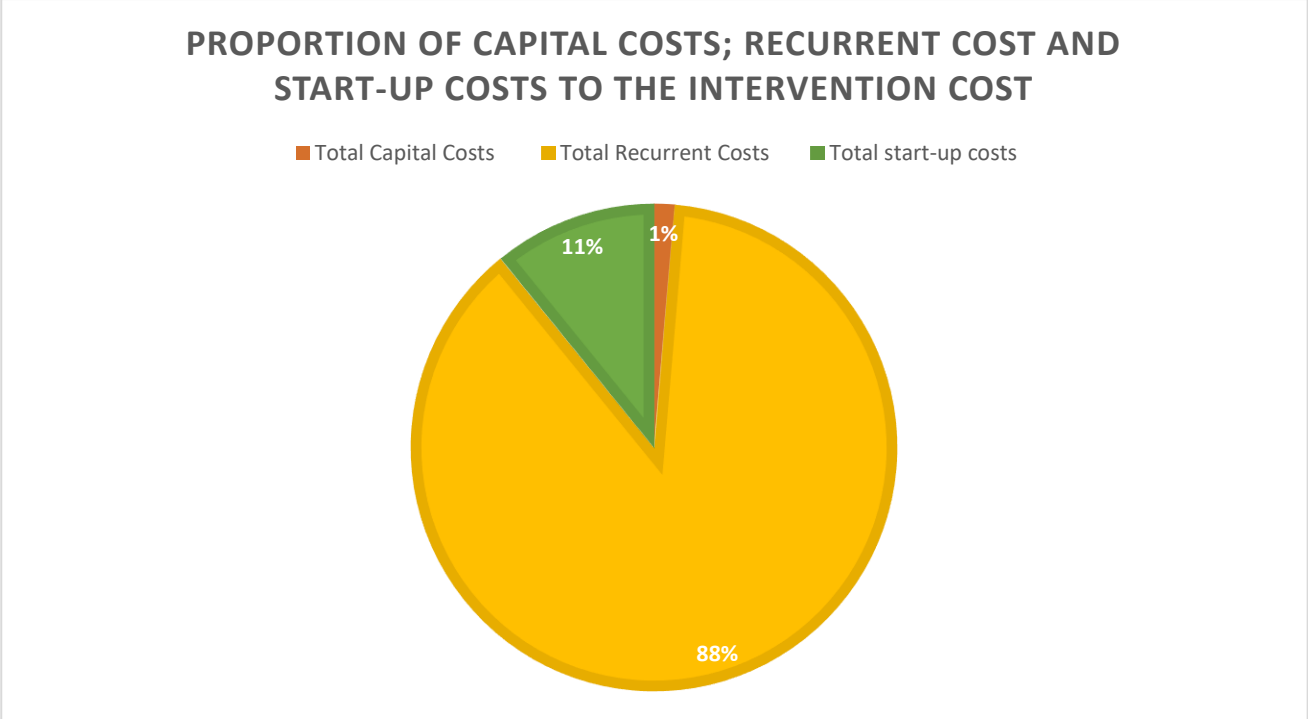


Figure 3.1: Pie chart representing the proportion of the total capital, recurrent and start-up costs to the total intervention costs

Table 5: Average Cost Per Month Per Clinic (ZAR, 2015)

	Name of Clinic			
Years	**Troy**	**Orange**	**Timber**	**Hillard**
Year 1[2]	R17,897.49	R18,064.33	R18,183.68	R18,426.51
Year 2	R13,629.17	R13,649.04	R13,629.17	R13,810.29

[2] The first year of the intervention is made up of costs gathered for the full year whilst the second year of the intervention are costs for 8months.

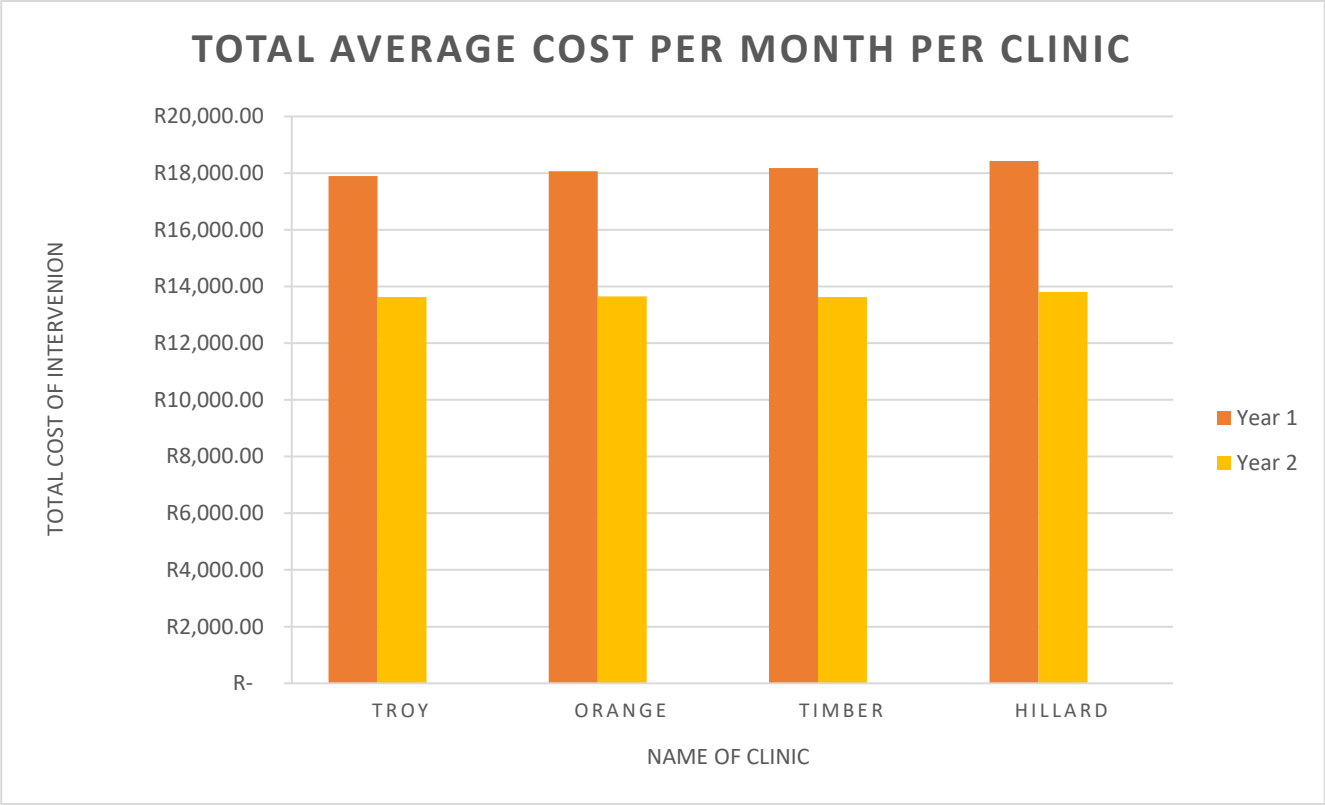


Figure 3.2: Bar graph showing the total average cost per clinic per month in the two-year period

Table 6: Total average number of patient visits per clinic (at end of intervention)

Clinic	**Total average number of patient visits per clinic (at end of intervention) in the period February 2014 - September 2015**	**Visits per nurse per month: at the end of intervention. Source:** (Limbani et al., 2019)	**Average number of nurses per clinic**
Troy	**90220**	**347**	**13**
Orange	**79296**	**413**	**6**
Timber	**25856**	**202**	**4**
Hillard	**68640**	**429**	**5**

The total average cost per patient per health facility per month, at the end of the intervention across all four clinics *was R6.30. The number of patients are calculated based on the visits per nurse per month as depicted in*

table 5. The number of visits per annum was calculated by multiplying the number of visits per nurse by the average number of nurses in each facility. Table 7 presents the average cost per patient from each clinic.

Table 7: Average Cost per patient per health facility per month (ZAR, 2015)

Clinic	**Average cost per patient per health facility per month**
Troy	R 3.59
Orange	R 4.11
Timber	R 12.66
Hillard	R 4.83

Timber clinic has seen less patients in the duration of the intervention relative to other clinics. According to the results from the process evaluation Timber clinic saw a decrease in the number of patients visiting the clinic. There was a 53% drop in the number of visits per nurse i.e., from 433 patients at baseline to 202 patients at the end of intervention.

3.2.2 Overall summary of analysis - combining costs and consequences

Table 8: Summary table of intervention costs, outcomes from the study, financial and descriptive consequences

Study Design	Cost Consequence Analysis Conducted in the Mpumalanga Province, Agincourt HDSS region, South Africa
Total Intervention Costs *Note that the final costs are presented in 2015[3] prices*	

[3] 2015 Average Inflation Rate was 4.5%

<table>
<tr><td>Total Start-Up Costs

R142 279.05 ($11,139.92)[5]</td><td colspan="2">Total Implementation Costs

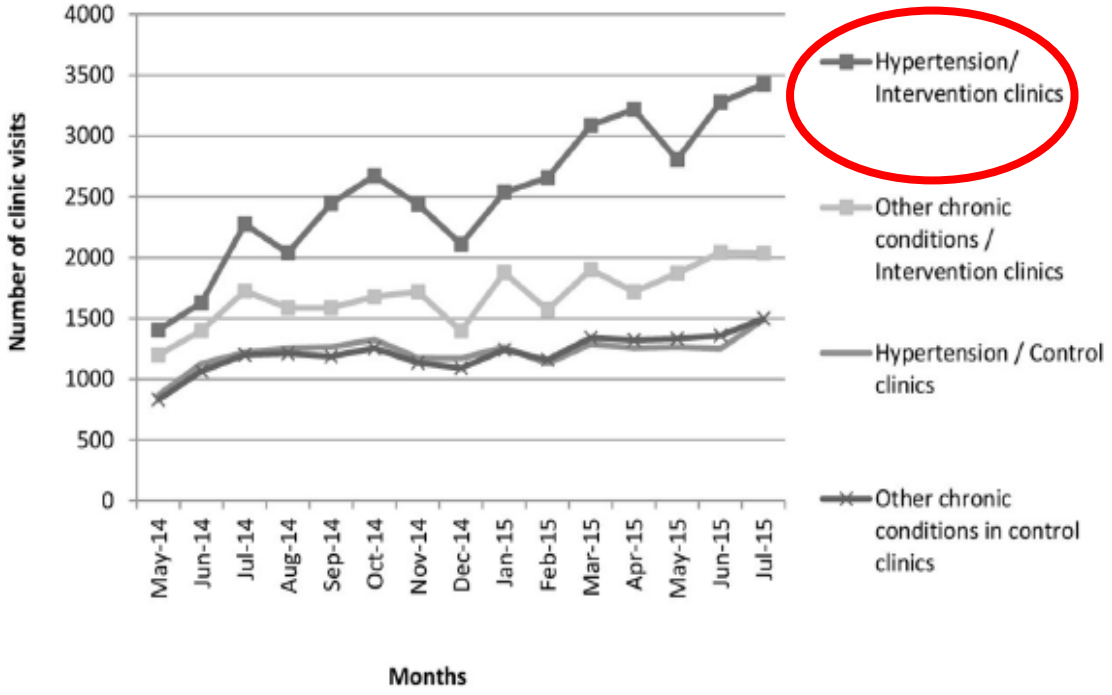
R1 308 605.24 ($102 458.91)[4]

Due to the control arm of the study following a do-nothing approach, the total intervention cost of the study will be the incremental cost of the intervention.
Average (mean) cost of the intervention per month across all four clinics for
Year 1: R18 143.00 ($1 420)[4]
Year 2: R13 679.41 ($1 071)[4]</td></tr>
<tr><td rowspan="2"></td><td>Total Capital Costs

R17 770.82 ($1,391.39)[5]</td><td>Total Recurrent costs

R1 148 555.37 ($89 927.60)[5]</td></tr>
<tr><td colspan="3">Study Outcomes</td></tr>
<tr><td>Outcome</td><td colspan="2">Description</td></tr>
</table>

[4] Conversion Rate the year 2015: 1USD = ZAR 12,772

Improved clinic attendance	These were total number of hypertensive patients visits per month. **Results** There was significantly a greater number of monthly visits from hypertensive and other chronic conditions patients in the clinics that had lay health workers. Hypertensive patients, however, were significantly greater than other chronic condition visits in these clinics (Goudge et al., 2018). See figure 3.4 below  Figure 3.3: Number of visits by hypertensive patients and other chronic conditions per month in the intervention and control clinics.
Improved attendance on scheduled appointments	This was the percentage of patients with hypertension that came to the clinic on their actual appointment dates. **Results** Over 75% of hypertensive patients attended clinic on scheduled date, compared to the 56% in the control clinics, which also suggested improved adherence. This was due to the reminders that hypertensive patients received from lay health workers via text messages and phone calls (Goudge et al., 2018).

Financial and Descriptive Consequences

Given that data to estimate long-term financial consequences were not gathered in the Nkateko Trial, it is challenging to determine exactly how outcomes from the trial translate into financial benefits. However, the intervention resulted in some evidence of increased clinic attendance, improved attendance on scheduled dates, reduced levels of blood pressure among clinic users with uncontrolled hypertension, and reduced waiting times in clinics. For instance, the waiting times reduced by one hour. Arguably, increased awareness of blood pressure control measures, such as clinic attendance which can be a proxy for medication adherence can result in financial benefits especially if it results in strokes averted. Descriptive consequences sought to describe the potential long-term health and other benefits that might result from increased attendance by patients with hypertension at the clinic.

Individual

A lot of patients stop seeking care due to the time spent in clinics. Lay health workers have been successful in reducing waiting times and thus allowing more patients to seek care. In the Nkateko trial this was seen as an increase in the number of patient visits (Goudge et al., 2018). In this trial there was a 1 hour decrease in waiting times in intervention clinics. That is, patients went from waiting for around 3 hours 20 min to around 2 hours 25 min (Limbani et al., 2019). Improved care-seeking could result in controlled hypertension amongst individuals, and this could result in lower incidences of stroke. Stroke is third leading cause of disability and the second highest cause of death in the world (W. Johnson et al., 2016).

Besides the improvement in clinic attendance and waiting times, the Nkateko trial found that there was an improvement in the blood pressure levels of the patients attending the intervention clinics, however the increase was not considered as significant. Factors like health education received from the lay health workers could have influenced this result. This is supported by a meta-analysis conducted in China using studies between 1991 to 2011 which found that health education interventions towards improving hypertension health outcomes reported an improvement in blood pressure control, marked by a significant decrease in systolic and diastolic blood pressure levels amongst participants (Xu et al., 2014).

Hypertension has been linked to productivity loss as people with hypertension usually succumb to stroke and the disability that may be associated with it. Therefore, the positive impact of the intervention such as improving clinic attendance and reducing waiting times in clinics, can have a positive impact in the society through improving hypertension health outcomes and thus improving productivity.

Health systems

There was an improvement in the provision of care in the Nkateko trial due to the use of lay health workers. They supported nurses with identifying 760 patients with high BP which resulted in half of them being diagnosed with hypertension (Goudge et al., 2018). As previously mentioned, hypertension is regarded as a silent killer and failure to diagnose it or if left untreated can lead to other conditions like stroke, heart failure and kidney failure. These two factors are the major drivers of CVD mortality and morbidity in Africa (Kayima et al., 2013).

A study by Maredza and Chola (2016) that was conducted in the same region as the Nkateko trial, in 2012, found that the cost of stroke treatment was R2.5–R4.2 million (US$283,500–US$485,000) annually and this represents 1.6 to 3% of the sub-district health expenditure. Treatment of hypertension can help reduce these costs. Although not directly assessed in this study, there are other potential financial benefits that could arise from the Nkateko intervention that can be translated into financial consequences. Based on the study which simulated the impact of lay health worker intervention in 10 years, it estimated that during 10 years of the CHW platform deaths averted would contribute, to the GDP, an additional R413 billion ($31 billion)[5] (Daviaud et al., 2018).

The Nkateko trial found that there was a 4.2% increase in the number of patients who had hypertension but was uncontrolled. That is, at baseline 8.8% were on treatment but uncontrolled and at the end of intervention that number increased to 13%. Though not significant, this is to show that the intervention somehow had an impact and that going forward can be improved by increasing the length of the study. A United States study that simulated a team-based care approach for the treatment of hypertension (aimed at individuals with treated but uncontrolled hypertension) expected a reduction of 4.7 million of individuals with uncontrolled hypertension in the 10-year timeframe. It will also lead to a reduction of 165 000 cardiovascular disease-related deaths (Dehmer et al., 2016). The Nkateko trial also found that there was a 6.7% increase in the number of patients who went on treatment. That is, at baseline there were 31.6% patients who were not on treatment but at the end of the intervention this number decreased to 24.7% (Goudge et al., 2018). Having people on treatment can improve their health status which may result in deaths averted. Based on the10-year life course model, the decreased risk of death per year among hypertension patients on treatment would translate into 6 588 less deaths (Daviaud et al., 2018).

[5] Conversion Rate the year 2018: 1USD = ZAR 13,2471

Macroeconomic

In 2011, the WHO and World Economic Forum (WEF) estimated that, economic losses will reduce by approximately US$ 377 billion (R2.7 trillion)[6] in LMICs over the period 2011-2025 should there be a 10% reduction in the mortality rate due to ischaemic heart disease and stroke (World Economic Forum, 2011).

Additionally, a study that explored educational and lifestyle modification intervention using lay health workers found the joint educational interventions cost from $62 to $114 (R825 to R1 517)[7] per patient per 1mmHg reduction in SBP, and to save 1 life-year in a year it was projected cost $13,986 (R186 091)[3] (Zhang et al., 2017).

[6] Currency conversion rate for the year 2011: 1USD = ZAR 7,2702

[7] Currency conversion rate for the year 2017: 1USD = ZAR 13,3209

4. Chapter Four: Discussion, Conclusion and Recommendations

4.1 Introduction

This section brings us to the final chapter of this research report. It summarizes the results of the study and provides a discussion thereof. The discussion follows the same sequence as that of the objectives listed in the methodology chapter. It first discusses the costs associated with the intervention and followed by the financial and descriptive consequences found in the research. It then discusses the strengths and limitations of the study. The last section of this chapter closes with a conclusion and recommendations.

4.2 Discussion

This study assessed the costs and consequences of using a lay health worker intervention for hypertension management within the context of the Nkateko Trial. It assessed the costs and consequences of deploying lay health workers to improve hypertension management particularly adherence to clinic attendance in primary health care facilities in South Africa.

Direct intervention costs

The study showed that to roll-out the intervention cost R1 308 605.24 ($102 458.91) in four clinics in rural Mpumalanga, over a period of two years. There were no significant differences in the total cost of intervention across all the intervention clinics. This can be explained by the fact that all clinics had the same number of lay health workers, with the same level of experience – which meant that remuneration was the same. They also received the same type of training. Also, the implementation manager worked across all four clinics which resulted in all the costs incurred by the manager to be averaged out across all four clinics.

The total average cost per patient per health facility per month, at the end of the intervention across all four clinics was R6.30 ($0.49). The average costs per patient per month ranged between R3.59 to R12,66 (which was almost triple the cost where patients who attended clinics were fewer). In terms of the average cost per health facility, Timber clinic had the highest cost per patient (R12.66). This was due to the decrease in the number of patients that the clinic saw during the course of the intervention. Timber clinic had the following challenges which might have affected patents' attendance: (i) there was limited space in the facility, (ii) poor relations

among patients and staff, and (iii) frustrated nurses due to limited space which led to a lack of commitment (Limbani et al., 2019).

The challenges faced at Timber Clinic highlight the importance of considering space constraints before deploying LHWs. Staff generally want to feel as if they have a working space to call their own. When this space is 'taken away' or shared with different cadre of workers without appropriate discussion this may lead to hostility. Poor relation between the staff and the patients at the other hand affects the quality of care delivered and may result in poor patient outcomes (Molina-mula & Gallo-estrada, 2020). This also has the potential to drive out patients from attending their appointments which may explain the decrease in attendance. Poor relations causes miscommunication of important information to patients which may result in poor health outcomes (HIPAA Jornal, 2021). Finally, the process evaluation by Limbani et al (2019) noted that clinics in the Nkateko Trial that performed well also had good managers and motivated nurses. It is therefore important to ensure that there is space (for lay health workers to work in), good nurse-patient relationship and motivated staff for the successful implementation of the lay health worker intervention.

Since the intervention of using lay health workers based in facilities was fairly a new concept in this region, there were some start-up costs that needed to be factored in. It therefore cost R142 279.05 ($11,139.92)[8] to prepare for the lay health workers to be deployed in health facilities. These start-up costs made up 10.9% of the total intervention costs. Start-up costs usually differ per intervention usually due the training that takes place. In the case of the Nkateko trial the training took place in an already existing site. They did not have to pay for venue costs. Hence there are no building costs. Since the trial was pragmatic, it was important for the costs to be as realistic as possible hence the building costs were not estimated. Other studies, depending on the number of lay health workers will need to factor in such costs. A study by George et al (2020) reported that venue costs for meetings with community health workers were 2% and 5% of the total cost for the intervention and control arm, respectively. These meetings consisted of fortnightly mentoring sessions and quarterly learning sessions with community health workers which works out to a total of 29 days in a 12month period (George et al., 2020).

[8] Conversion Rate the year 2015: 1USD = ZAR 12,772

As noted in the literature review, South Africa currently uses lay workers outside health facilities. Therefore, these results should be taken into account when considering how to conduct costing for a facility based lay health worker and most importantly, which cost inputs to consider for such a costing analysis. The growing need of health care workers is often not looked at with the financial need to remunerate such cadre of workers. This research gives an idea of how much it will cost to incorporate the use of lay health workers in rural primary health care facilities, based on data collected in Mpumalanga region. These results also inform the end user about where the bulk of the costs lie when it comes to implementing such an intervention.

Also, the breakdown of costs by function allows the reader to see which function accounted for many costs, in this case the personnel costs – which is in congruent with other studies. The bulk of the costs were from recurrent costs (mainly salaries) which made up 87.8.% of the total intervention costs. Personnel costs made up 60% of the recurrent costs. The latter is supported by findings from similar studies. For example, a study evaluating the "Costs associated with the use of lay heath workers to improve patient uptake and retention in the Prevention of Mother to Child Transmission services (PMTCT)" found that it would cost around R130 718 for a clinic to use this intervention and the bulk of the costs were incurred from personnel salaries (Zeelie, 2014). At the other hand, capital costs were only 1.4% of the total intervention costs. From the budgetary perspective, this study can help facilities gauge how they can budget for such interventions and how they can use their resources to minimize wastage. The PMTCT study was a "cost analysis of facility based lay health workers focused on improving HIV health outcomes for HIV positive women and children" (Zeelie 2014). It was also a task shifting intervention. Tasks were shifted from professional heath workers and nurses, to lay health workers. The author found that it would cost R130 718 p.a per clinic to roll out a facility based lay health worker for HIV PMTCT intervention whilst this research report found that it will cost R54 000 p.a per clinic for the rollout of facility based lay health workers for the hypertension management.

The PMTCT study does not conclude on whether it was cost effective or not. However, it concluded that scaling up of the intervention in the Free State province would account for 0.012% of the South African National Treasury expenditure. Free State has a total of 220 primary health care facilities and Mpumalanga has an estimated 289 primary health care facilities. Therefore, considering that the cost per clinic for the hypertension

intervention is equal to 41% of the HIV PMTCT intervention and based on the marginal percentage cost of 0.012% calculated in Free State, this suggests that using lay health workers for hypertension management may be an affordable intervention.

Currently South Africa has seen a significant decrease in the number of deaths accounted for by HIV (Maluleke, 2016). The remarkable progress made in addressing the HIV epidemic has been attributed to several factors including: a research agenda that prioritises HIV/AIDS, an increase in human workforce capacity, the use of lay health workers to support patients and greater investment in cost-effective prevention and treatment approaches. Lessons from the success of the HIV interventions in primary healthcare facilities can be used to improve hypertension management in low- to- middle income countries.

Addressing Financial and Descriptive consequences

Health worker shortages continue to be a problem and NCDs such as hypertension continue to rise. Due to the nature of systems, such as the health system, when there is a shortfall in one area, whole system will be affected. Failure to address the shortage of health workers may, to a certain extent, adversely affect improvements in NCDs.

These group of diseases are the leading cause of death in the working-age group therefore "addressing NCDs like hypertension are crucial for better economic growth" (Hofman, 2014). Improvement of these health outcomes can translate into potential health savings. For instance, the cost of treating stroke (R2.5–R4.2 million) in rural Mpumalanga can be saved and diverted to further fund hypertension management interventions. Also, through treatment of hypertension, deaths can be averted which can translate to financial gains through boosting the country's GDP (Daviaud *et al.*, 2018).

The use of lay health workers has been proven to be effective in improving health outcomes of different diseases e.g., malaria and HIV interventions and programme outcomes (Bowser et al., 2015). A systematic review of the lay health worker intervention trials by Lewin et al., (2006) also found that the use of lay health workers resulted in improved disease outcomes on programmes like TB management and promoting immunization. In the

Nkateko trial approximately 11.3% were on treatment and had controlled hypertension at the end of intervention compared to 6.6% at baseline (Goudge et al., 2018).

Not only does the use of lay health worker assist in improving health outcomes, it also assists in addressing the shortage of health workers. Tasks are spread out which helps in reducing the burden felt by other staff members, like nurses. In terms of cost, drawing in from literature, task shifting to lay heath workers for hypertension management in South Africa is deemed to be effective and highly cost effective (Abrahams-Gessel et al., 2016). Another study by Joshi et al (2014) supports the claim that task shifting is effective and cost effective for the management of non-communicable diseases like hypertension. This claim is further supported by a systematic review conducted by Mdege et al (2013) which concluded that task shifting from health professionals to lay health workers or doctors to nurses can "result in substantial cost savings" in low-middle income areas.

Other important ways to improve chronic disease management include human resources strengthening, through task sharing and capacitation (South African Ministry of Health, 2013).In the Nkateko trial, this resulted in reduced waiting times in the intervention clinics.

The indirect effect of improving waiting times in clinics is that it does not lead to greater income loss to individuals (seeking care) who earn hourly rates at work (Chu et al., 2019). Therefore, as part of the ideal clinic intervention, improving waiting times in clinics is part of improving quality of care (Egbujie et al., 2018). Thus, making it imperative for clinics to strive for shorter waiting times and fast processes.

In the Nkateko trial, the use of lay health workers was instrumental in bringing about positive changes. The facilities saw an increase in the number of patients using the clinics. There was improved clinic attendance by patients with chronic conditions (with and without hypertension). However, there were a greater number of hypertensive patients attending in the clinics. This could be attributed to hypertensive patients receiving visit reminders prior to coming to the clinic. This finding is supported by the increase in the number of hypertensive patients attending on their scheduled dates. Over 75% of hypertensive patients attended clinic on their scheduled date in clinics with lay health workers. Patient attendance can be used as a proxy for adherence to medication. This is based on the assumption that the refill of the prescription when attending the clinic is linked

to “medication-taking behaviour”(Anghel et al., 2019). Improvement in clinic attendance can therefore mean, in a long term, an improvement in hypertension health outcomes.

Lay health workers in clinics also provided health education which can also be linked to creating awareness and thus influencing attendance. As a result of health education, patients can be aware of hypertension and how to manage it. Besides the cost’s aspect for treatment of hypertension, people should be educated on the risk factors, treatment, and management of hypertension. The high prevalence and lack of awareness of hypertension suggests more work needs to be done in health promotion. The increasing numbers of untreated and unidentified hypertension at the other hand suggests that more screening needs to be done, and the high rates of hypertension that is not managed suggest that better care in facilities is needed. A scoping review conducted in Africa for programs using lay health workers to improve HIV prevention of mother to child transmission (PMTCT), found the use lay health workers was effective to improve community awareness of the mother-to-child transmission, clinic attendance and retention of infected persons (Schmitz et al., 2019).

However, these approaches to population health should not be a blanket approach but designed to meet the specific needs of a specific population. Take for instance a study conducted by Jongen et al (2019) indicated that due to poverty, people in rural Limpopo could not afford to change their type of diet to meet the standards required for a healthy lifestyle. In terms of health promotion, prevention, and early treatment, it is essential for countries to select the relevant combination of treatment and prevention strategies with their associated impact and costs (Kankeu et al., 2013).

One study that evaluated the cost effectiveness of such an intervention in South Africa (but with LHWs deployed in communities) found that it was cost effective (Gaziano et al., 2014). The use of lay heath workers in the communities benefits (i) the individual in that it reduces the cost of travelling to the health facilities and (ii) the health system in that it will reduce the number of patients physically present at primary health care facilities. In that case it will address overcrowding in health facilities and also alleviate the burden felt as a result of understaffing. This intervention found that it will cost $8 (R121.00 based on 2014 exchange rates) per patient

per year (Gaziano et al., 2014). The facility lay health worker intervention reported in this research found that it cost $5 (R75) per patient per year.

Finally, at the macrolevel, research suggest that investing in the health of the individuals in a country means investing in economic growth. There is a correlation in health of the state and its productivity gains (Tompa, 2002). Diseases like hypertension, as stated in the literature, affect the working age group. Therefore, not taking care of it will have ripple effects which will result in affecting the economy. With the increase in the unemployment rate in South Africa, the country cannot afford to further lose its people to hypertension and other CVD related illnesses.

This is the first study that focused on using a cost consequence analysis to evaluate the costs and consequences of using facility based lay health workers to improve adherence to clinic attendance in rural primary health care facilities in the Mpumalanga province, Bushbuckridge sub-district. It is also the first that looked at task sharing from the nurses to lay health workers with the associated costs. The study had several strengths, and these include the following: using real expenditure data that was collected prospectively in the running of the RCT, and capturing a broad range of costs to inform the intervention cost analysis Missing data was not a challenge in this study which strengthened the costing analysis. Incorrect conclusions can be reached when the proportion of missing data is too high (Kang, 2013). The cost breakdown allowed for ease of comparability with other interventions. Given that the end user wants to implement such a study they can easily tailor make their costing to suit their needs based on the structure provided.

Another strength is that the chosen method of analysis, cost consequence, aided in providing a broad range of health and non-health related costs and benefits (Hunter & Shearer, 2014). A strength associated with the method of economic evaluation is that it offers the decision-makers a choice to select the outcome that is most relevant to them and consider that alongside the reported costs.

There are some limitations to note. Contrary to the latter, the method does not identify a single outcome measure, like QALYs or DALYs, which may be a challenge for decision making in terms of identifying whether the intervention was cost effective or not. Another limitation, as identified in the methods section, was that the

literature review for objective two was not comprehensive but it gave a useful overview of the descriptive and financial consequences. Other important cost drivers like building costs were not included but may need to be factored in for future studies as space constraints was a key issue at one of the facilities.

Recommendations

Future research should explore the relationship between intermediate health outcomes reported in this study and final health outcomes (e.g. stroke prevention) through, potentially, modelling techniques. Furthermore, it is worthwhile to consider a cost-utility analysis that reports the incremental cost-effectiveness ratios (cost per QALY or cost per DALY). The latter will provide more conclusive evidence about the intervention's cost-effectiveness compared to that of other programmes. Drawing from my experience of working as a facility and community based lay health worker another recommendation could be for further research to be conducted to evaluate the effectiveness of integrating facility based lay health workers and community based lay health workers (from WBOTs) on improving hypertension health outcomes. This will be based on the assumption that by having lay health workers out in the field for community education, hypertension screening and at the facility, can help create awareness, increase reach and improve adherence, respectively.

Conclusion

This study aimed to estimate the costs of deploying lay health workers in facilities to improve hypertension management and to present these costs alongside clinical outcomes and financial benefits (observed and perceived). The study showed that using lay health workers offers a potentially promising low-cost means to intervene to significantly reduce waiting times at health facilities and to improve intermediate health outcomes in patients with hypertension. Moreover, interventions that use facility based LHWs could have impacts that extend beyond the health system including positive impacts on the macroeconomy. However, further studies are needed to investigate the link between improvement in intermediate health outcomes and the macroeconomic impacts within the context of South Africa.

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5. Appendices

Appendix One: Cost data collecting sheet

Table 9: Data Collecting Sheet: Presentation of the Total costs per clinic, cost per line item, per category and the total intervention costs

	Health Facility Name				
Item	Troy	Orange	Timber	Hillard	Total
Start-up Costs (February 2014 -April 2014)					
Material development and training cost					
Lay Health Workers (Initial Training)					
Recruitment Activities					
Total Start-Up Costs					
Capital Costs (February 2014 – January 2015)					
Cell phones and Lay Health Worker Uniforms					
Office Equipment					
Total Capital Costs					
Recurrent Costs (February 2014 – January 2015)					
Vehicle (Hired vehicle cost)					

	Health Facility Name				
	Troy	Orange	Timber	Hillard	Total
Capital Costs (January 2015 - September 2015)					
Recurrent Costs (January 2015 - September 2015)					

Personnel (Lay Health workers										
Personnel (Implementation Manager)										
Training										
Transport Operating Costs										
Consumables (Office supplies, airtime,)										
Stationery										
Repairs and Maintenance										
Rent										
Security										
Vehicle Operation and Maintenance										
Total Recurrent Costs										
Total Costs for Intervention Y1; Y2 & Y3										

Appendix Two: Report on search terms and Data base used

Report on literature review Search Terms and Databases used		
Item	Search Terms Used	Study Sources Used
Descriptive Consequences	"strokes averted"; "life years gained"; "improved quality of life"; "hypertension management health benefits" (other studies referred to hypertension as high blood pressure) and "productive years of work" followed by terms like treatment of hypertension. Other literature focused on productivity losses and loss of earnings as a result of work absences due to care-taking (Daviaud et al., 2018).	Google Scholar BMJ Global Health BMC Neurology BMC Family Practice Cardiovascular Journal of Africa The Lancet Global Health National Library of Medicine South African Medical Journal American Journal of Preventative Medicine African Journal of Primary Healthcare and Medicine Health Education Journal Journal of Governance and Regulation Journal of Community Health BMC Public Health PLoS One The Lancet Journal of American Heart Association Human Sciences Research Council SAGE Journals Annual Review of Clinical Psychology Web Search Engine Grey Literature (Government websites) Reference Tracking Contact with experts
Financial Consequences	"hypertension economics"; "costs of treating strokes"; "non-communicable diseases"; "NCDs budget allocation"; "cost analysis"; "lay health workers cost"; "cost of illness"; "cost per missed appointment" and (('non-attendance' OR 'defaulted' OR 'no show') AND ('appointment' OR 'follow-up') AND ('hypertension' OR 'high blood pressure') AND ('family practice' OR 'clinic') AND ('economic cost' OR 'cost-saving' OR 'costs'))	

Appendix Three: Plagiarism Declaration

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

FACULTY OF HEALTH SCIENCES

PLAGIARISM DECLARATION TO BE SIGNED BY ALL HIGHER DEGREE STUDENTS

SENATE PLAGIARISM POLICY: APPENDIX ONE

I Dineo Mothlele (Student number: 707856) am a student registered for the degree of Master of Public Health in the field of Health Economics in the academic year 2021.

I hereby declare the following:

- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
- I confirm that the work submitted for assessment for the above degree is my own unaided work except where I have explicitly indicated otherwise.
- I have followed the required conventions in referencing the thoughts and ideas of others.
- I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.
- I have included as an appendix a report from "Turnitin" (or other approved plagiarism detection) software indicating the level of plagiarism in my research document.

Signature:  Date: 23 November 2021

Appendix Four: Ethics clearance certificate

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

R14/49 Mrs D Mothlele

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M200703

NAME: (Principal Investigator)	Mrs D Mothlele
DEPARTMENT:	School of Public Health Medical School University
PROJECT TITLE:	Cost consequence analysis of facility-based lay health worker intervention to improve hypertension management in rural South Africa
DATE CONSIDERED:	2020/07/31
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	Prof J Goodge; Drs M Maredza & F Limbani
APPROVED BY:	Dr CB Penny, Chairperson, HREC (Medical)
DATE OF APPROVAL:	2020/10/30

This clearance certificate is valid for 5 years from the date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd Floor, Phillip Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.
I/we fully understand the conditions under which I am/we are authorized to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to submit details to the Committee. **I agree to submit a yearly progress report**. When a funder requires annual re-certification, the application date will be one year after the date when the study was initially reviewed. In this case, the study was initially reviewed in **July** and will therefore reports and re-certification will be due early in the month of **July** each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

30/11/2020
Date

Appendix Five: Ethics waiver letter

The Centre for Health Policy

UNIVERSITY OF THE WITWATERSRAND JOHANNESBURG

26 June 2020

Dear Ethics committee

Applications for ethics waivers for secondary analysis of the Ntaketo trial data
This letter is motivate for an ethics waiver for three masters students: Dineo Mothlele, Manape Kgopa, and Mando Malebo

They are each using some of the Ntakeko trial data to do a secondary data analysis study, which was conducted between 2013-2017

Attached is the ethics certificate for the trial

As the Wits PI on the trial I give permission for these students to use the data.

Kindest regards

Jane Goudge

Professor Jane Goudge
Director of the Centre for Health Policy

Health Policy and Systems Research

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